US3752245 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

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US3752245
Form: Participant Creation
Data signed: (b) (4) **12 Feb 2021 19:04:08**
Generated On: 10 Jun 2021 09:46:43

Participant ID	US3752245

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3177471

US3752245
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	SCRN

FDA-CBER-2022-1614-3177472

US3752245
Folder: Screening
Form: Demographics
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-3177473

US3752245
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177474

US3752245
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Did the participant meet all eligibility criteria?	Yes ■ No ☐

FDA-CBER-2022-1614-3177475

US3752245
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-3177476

US3752245
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	HYPERLIPIDEMIA
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)	

FDA-CBER-2022-1614-3177477

US3752245
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	ASTHMA
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)	

FDA-CBER-2022-1614-3177478

US3752245
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	DIABETES MELLITUS TYPE II
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)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3177479

US3752245
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	URINARY INCONTINENCE
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3177480

US3752245
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177481

US3752245
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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

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US3752245
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	OBSTRUCTIVE SLEEP APNEA
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)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752245
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

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US3752245
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1974
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 1974
Stop Year (derived)	1974

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US3752245
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	COLONOSCOPY
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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US3752245
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	COLONOSCOPY
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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US3752245
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	BREAST BIOPSY (UNKNOWN IF BENIGN OR MALIGNANT)
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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US3752245
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	BREAST BIOPSY (UNKNOWN IF BENIGN OR MALIGNANT)
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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US3752245
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	APPENDECTOMY
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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US3752245
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	JOINT PAIN (LOCATION AND ASSOCIATED MEDICAL CONDITION UNKNOWN)
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752245
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	TENDINITIS BILATERAL WRISTS
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752245
Folder: Screening
Form: Medical History (17)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752245
Folder: Screening
Form: Medical History (18)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Condition	NAPROXEN ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3177494

US3752245
Folder: Screening
Form: Medical History (19)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177495

US3752245
Folder: Screening
Form: Medical History (20)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Condition	PREVIOUS CEREBROVASCULAR ACCIDENT
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3177496

US3752245
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	13:24 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 13:24
Height *(xxx.x)*	162.0 cm
Weight *(xxx.x)*	95.4 kg
BMI *(xxx.x)*	36.35117 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)	

FDA-CBER-2022-1614-3177497

US3752245
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	25 AUG 2020

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

FDA-CBER-2022-1614-3177498

US3752245
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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)*	UN UNK 1979
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-3177499

US3752245
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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

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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)	False
Other	False
Specify	

US3752245
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-3177502

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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What was the date of randomization? *(dd MMM yyyy)*	25 AUG 2020
What was the participant's randomization number?	188125
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 ■

FDA-CBER-2022-1614-3177503

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Height	ND - Not Done
Weight	ND - Not Done

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US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	13:24 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 13:24
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	080 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3177505

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	15:10 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:10
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3177506

US3752245
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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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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US3752245
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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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)*	14:37 (24 HR)
Treatment Date and Time (derived)	25 AUG 2020 14:37
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3752245
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	25 AUG 2020
Collection time *(00:00-23:59)*	13:44 (24 HR)
Collection date and time (derived)	25 AUG 2020 13:44

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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	13:41	25 AUG 2020 13:41
Nasopharyngeal Swab 2	No		

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US3752245
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177511

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 AUG 2020 15:01
PC Open Date & Time	25 AUG 2020 14:57
PC Close Date & Time	25 AUG 2020 17:27

FDA-CBER-2022-1614-3177512

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	26 AUG 2020 06:03
PC Open Date & Time	25 AUG 2020 18:22
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-3177513

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	26 AUG 2020 12:55
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3177514

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 AUG 2020 14:24
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-3177515

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	28 AUG 2020 20:59
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3177516

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.3 °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	29 AUG 2020 14:52
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3177517

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	31 AUG 2020 15:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-3177519

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 AUG 2020 15:02
PC Open Date & Time	25 AUG 2020 14:57
PC Close Date & Time	25 AUG 2020 17:27

FDA-CBER-2022-1614-3177520

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 AUG 2020 06:04
PC Open Date & Time	25 AUG 2020 18:22
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-3177521

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 AUG 2020 12:55
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3177522

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43

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 14:24
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-3177523

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
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 21:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3177524

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
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 14:52
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3177525

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	30 AUG 2020 12:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-3177526

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	31 AUG 2020 15:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-3177527

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 ☐

FDA-CBER-2022-1614-3177528

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	25 AUG 2020 15:03
PC Open Date & Time	25 AUG 2020 14:57
PC Close Date & Time	25 AUG 2020 17:27

FDA-CBER-2022-1614-3177529

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 ☐

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	26 AUG 2020 06:04
PC Open Date & Time	25 AUG 2020 18:22
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-3177531

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 2
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177532

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	26 AUG 2020 12:56
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3177533

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 3
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177534

	Yes ☐
PC Time stamp	27 AUG 2020 14:25
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 4
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

FDA-CBER-2022-1614-3177536

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43

	Yes
PC Time stamp	28 AUG 2020 21:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3177537

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 5
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177538

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	29 AUG 2020 14:52
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3177539

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 6
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177540

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177541

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 7
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177542

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	31 AUG 2020 15:26
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3752245
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	3 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177544

US3752245
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177545

US3752245
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:01**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177546

US3752245
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:01**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177547

US3752245
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

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	

FDA-CBER-2022-1614-3177548

US3752245
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177549

US3752245
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT2

FDA-CBER-2022-1614-3177550

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	06 OCT 2020
Time of assessment *(00:00-23:59)*	12:40 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 12:40
Temperature *(xxx.x)*	99.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3177551

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	06 OCT 2020
Time of assessment *(00:00-23:59)*	13:45 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 13:45
Temperature *(xxx.x)*	99.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3177552

US3752245
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	06 OCT 2020

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

FDA-CBER-2022-1614-3177553

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	6 OCT 2020
What was the treatment time? *(00:00-23:59)*	13:30 (24 HR)
Treatment Date and Time (derived)	6 OCT 2020 13:30
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

FDA-CBER-2022-1614-3177554

US3752245
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	06 OCT 2020
Collection time *(00:00-23:59)*	12:59 (24 HR)
Collection date and time (derived)	06 OCT 2020 12:59

FDA-CBER-2022-1614-3177555

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Collection date *(dd MMM yyyy)*	06 OCT 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:57	06 OCT 2020 12:57
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3177556

US3752245
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177557

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 13:51
PC Open Date & Time	06 OCT 2020 13:50
PC Close Date & Time	06 OCT 2020 16:20

FDA-CBER-2022-1614-3177558

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 17:16
PC Open Date & Time	06 OCT 2020 17:15
PC Close Date & Time	07 OCT 2020 11:59

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 OCT 2020 13:01
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °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	09 OCT 2020 05:04
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-3177561

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °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	09 OCT 2020 12:00
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-3177562

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

FDA-CBER-2022-1614-3177564

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	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	12 OCT 2020 19:11
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 OCT 2020 13:52
PC Open Date & Time	06 OCT 2020 13:50
PC Close Date & Time	06 OCT 2020 16:20

FDA-CBER-2022-1614-3177566

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 OCT 2020 17:17
PC Open Date & Time	06 OCT 2020 17:15
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-3177567

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 OCT 2020 13:02
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43

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	09 OCT 2020 05:05
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-3177569

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
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	09 OCT 2020 12:01
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-3177570

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

FDA-CBER-2022-1614-3177571

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

FDA-CBER-2022-1614-3177572

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	12 OCT 2020 19:11
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

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 ☐

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 OCT 2020 13:52
PC Open Date & Time	06 OCT 2020 13:50
PC Close Date & Time	06 OCT 2020 16:20

FDA-CBER-2022-1614-3177575

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 ☐

FDA-CBER-2022-1614-3177576

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 OCT 2020 17:17
PC Open Date & Time	06 OCT 2020 17:15
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-3177577

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 2
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177578

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	07 OCT 2020 13:03
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-3177579

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 3
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177580

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	09 OCT 2020 05:06
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-3177581

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 4
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177582

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	09 OCT 2020 12:01
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-3177583

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 5
HEADACHE	None ☐
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ☐
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ☐
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

FDA-CBER-2022-1614-3177584

	Yes ☐
PC Time stamp	
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 6
HEADACHE	None ☐
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ☐
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ☐
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

FDA-CBER-2022-1614-3177586

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

FDA-CBER-2022-1614-3177587

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 7
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3177588

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43

	Yes ☐
PC Time stamp	12 OCT 2020 19:12
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

FDA-CBER-2022-1614-3177589

US3752245
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177590

US3752245
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177591

US3752245
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177592

US3752245
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177593

US3752245
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177594

US3752245
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177595

US3752245
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:05:03**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	03 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-3177596

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 19:05:03**
Generated On: 10 Jun 2021 09:46:43

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	03 NOV 2020
Time of assessment *(00:00-23:59)*	10:45 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 10:45
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752245
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:05:03**
Generated On: 10 Jun 2021 09:46:43

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	03 NOV 2020

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

FDA-CBER-2022-1614-3177598

US3752245
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:05:03**
Generated On: 10 Jun 2021 09:46:43

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	03 NOV 2020
Collection time *(00:00-23:59)*	10:47 (24 HR)
Collection date and time (derived)	03 NOV 2020 10:47

FDA-CBER-2022-1614-3177599

US3752245
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:03**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177600

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 ☐

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

FDA-CBER-2022-1614-3177602

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 ☐

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

FDA-CBER-2022-1614-3177604

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 NOV 2020 13:24:17
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

FDA-CBER-2022-1614-3177605

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	22 NOV 2020 08:55:52
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

FDA-CBER-2022-1614-3177606

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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 04:11:03
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-3177607

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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 05:12:03
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

FDA-CBER-2022-1614-3177608

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 14:02:05
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-3177611

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 15:13:28
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 11:13:52
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-3177613

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 11:58:18
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

FDA-CBER-2022-1614-3177614

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 09:40:34
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

FDA-CBER-2022-1614-3177615

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 09:34:14
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this 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	01 FEB 2021 15:07:25
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

FDA-CBER-2022-1614-3177617

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 10:32:03
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

FDA-CBER-2022-1614-3177618

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 02:21:45
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

FDA-CBER-2022-1614-3177619

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 22:50:44
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

FDA-CBER-2022-1614-3177620

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 05:09:10
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

FDA-CBER-2022-1614-3177621

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 11:31:52
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

FDA-CBER-2022-1614-3177622

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177624

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 07:18:49
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

FDA-CBER-2022-1614-3177625

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-3177626

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177627

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 07:29:57
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

FDA-CBER-2022-1614-3177628

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 08:29:22
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

FDA-CBER-2022-1614-3177629

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 23:07:52
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

FDA-CBER-2022-1614-3177630

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 10:25:07
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

FDA-CBER-2022-1614-3177631

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 04:36:53
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

FDA-CBER-2022-1614-3177632

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 MAY 2021 00:01
Patient Cloud Close Date & Time	10 MAY 2021 23:59

FDA-CBER-2022-1614-3177634

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ☐

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

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177638

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 09:46:43

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177646

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3177647

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177648

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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 ≥ 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-2022-1614-3177649

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177652

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177655

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177656

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177658

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177660

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177664

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3177665

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177666

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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 ≥ 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	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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-2022-1614-3177671

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177672

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177675

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

FDA-CBER-2022-1614-3177676

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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 ☐

FDA-CBER-2022-1614-3177677

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177678

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177680

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177682

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177684

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177685

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177686

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177688

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177690

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177692

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177693

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

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177698

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177700

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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-2022-1614-3177705

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177708

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

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 ☐

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

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

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

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 ☐

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3177725

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 MAR 2022 00:01
Patient Cloud Close Date & Time	04 APR 2022 23:59

FDA-CBER-2022-1614-3177728

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177730

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177733

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177734

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

FDA-CBER-2022-1614-3177736

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 ≥ 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	05 MAY 2022 00:01
Patient Cloud Close Date & Time	09 MAY 2022 23:59

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3177741

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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 ☐

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177745

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177746

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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177748

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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 ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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

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 ☐

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Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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

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 ☐

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

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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 ☐

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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 ≥ 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 ☐

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

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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 ☐

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

FDA-CBER-2022-1614-3177768

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

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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 ≥ 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 ☐

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

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-3177774

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 ≥ 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 ☐

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

FDA-CBER-2022-1614-3177776

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 ☐

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Generated On: 10 Jun 2021 09:46:43

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

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

FDA-CBER-2022-1614-3177780

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

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

FDA-CBER-2022-1614-3177782

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3177785

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

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

FDA-CBER-2022-1614-3177788

US3752245
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:46:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 11:32:05

FDA-CBER-2022-1614-3177789

US3752245
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177790

US3752245
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:05:02**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177791

US3752245
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:04:11**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	04 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177792

US3752245
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:04:11**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177793

US3752245
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:05:01**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177794

US3752245
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:04:11**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177795

US3752245
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **14 Mar 2021 18:09:08**
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	02 MAR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177796

US3752245
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **14 Mar 2021 18:09:08**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177797

US3752245
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT4

FDA-CBER-2022-1614-3177798

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	29 MAR 2021
Time of assessment *(00:00-23:59)*	11:30 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 11:30
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3177799

US3752245
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	29 MAR 2021

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

FDA-CBER-2022-1614-3177800

US3752245
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	29 MAR 2021
Collection time *(00:00-23:59)*	11:41 (24 HR)
Collection date and time (derived)	29 MAR 2021 11:41

US3752245
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3177802

US3752245
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43

Was Contact Attempted?	Yes ☐
	No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	
Please select one status for the follow-up contact	Contact Made ☐
	Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3177803

Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **12 Feb 2021 19:04:09**
Generated On: 10 Jun 2021 09:46:43

Date of Contact	10 DEC 2020
Time of Contact	13:30
Date and Time of Contact (derived)	10 DEC 2020 13:30
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 ☐

FDA-CBER-2022-1614-3177805

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

Symptom Day

- [x] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	7 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.4 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- Day 1 ☐
- Day 2 ■
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177810

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	8 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ■
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177814

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	9 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ■
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	10 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177820

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ■
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177822

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	11 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-3177824

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177825

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ■
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177826

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.6 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177828

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177829

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ■
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177830

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	13 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-3177832

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177833

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ■
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177834

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	14 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177837

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ■
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177838

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	15 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **20 Mar 2021 01:42:09**
Generated On: 10 Jun 2021 09:46:43

	Not Done ☐
Fatigue	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177841

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

FDA-CBER-2022-1614-3177842

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	16 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177845

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ■
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3177846

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	17 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3177849

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **12 Feb 2021 19:04:09**
Generated On: 10 Jun 2021 09:46:43

Date of Visit	11 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ■
Date of Test	11 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **12 Mar 2021 16:21:35**
Generated On: 10 Jun 2021 09:46:43

Generate Next COVID-19 Assessment	Yes ■ No ☐

FDA-CBER-2022-1614-3177851

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 DEC 2020
Day 5	Yes	15 DEC 2020
Day 7	Yes	17 DEC 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3752245
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-3177853

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	11 DEC 2020
Time of assessment *(00:00-23:59)*	10:05 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 10:05
Height *(xxx.x)*	63.0 in
Weight *(xxx.x)*	210.0 lb
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3177854

US3752245
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	11 DEC 2020

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

FDA-CBER-2022-1614-3177855

US3752245
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	11 DEC 2020

FDA-CBER-2022-1614-3177856

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	20 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-3177857

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **22 Apr 2021 15:26:15**
Generated On: 10 Jun 2021 09:46:43

Date of updated informed consent *(dd MMM yyyy)*	20 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)*	20 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	

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	20 JAN 2021
Collection time *(00:00-23:59)*	13:20 (24 HR)
Collection date and time (derived)	20 JAN 2021 13:20

FDA-CBER-2022-1614-3177859

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **12 Feb 2021 19:04:10**
Generated On: 10 Jun 2021 09:46:43

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	20 JAN 2021
Collection time *(00:00 - 23:59)*	13:16
Collection Date and Time (derived)	20 JAN 2021 13:16

FDA-CBER-2022-1614-3177860

US3752245
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Feb 2021 19:04:08**
Generated On: 10 Jun 2021 09:46:43

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-3177861

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **29 Apr 2021 22:28:36**
Generated On: 10 Jun 2021 09:46:43

AEID	USA-US113-2020-MRNA-1273-P30 1000009
Adverse event	BELL'S PALSY
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 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)*	29 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	True
Hospital Admission Date *(dd MMM yyyy)*	6 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	7 NOV 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

FDA-CBER-2022-1614-3177862

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

Narrative

	SUBJECT WAS ADMITTED TO HOSPITAL 06NOV2020 TO RULE OUT STROKE. CT WAS INCONCLUSIVE BUT ACCORDING TO THE SUBJECT THE MRI SHOWED NO EVIDENCE OF CURRENT, ACUTE STROKE BUT DID SHOW POSSIBLE STROKE IN THE PAST. SHE IS BEING TREATED FOR BELL'S PALSY AND WAS ALSO PRESCRIBED PLAVIX DUE TO POSSIBLE STROKE HISTORY. SHE FOLLOWS UP WITH HER PCP THIS WEEK TO DETERMINE LONG-TERM MANAGEMENT. HAD COMPLETE PARALYSIS. UNILATERAL FACIAL DROOP
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

FDA-CBER-2022-1614-3177864

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **29 Apr 2021 22:28:36**
Generated On: 10 Jun 2021 09:46:43

AEID	
Adverse event	NASAL CONGESTION
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)*	7 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)*	15 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	

FDA-CBER-2022-1614-3177865

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)	

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **29 Apr 2021 22:28:36**
Generated On: 10 Jun 2021 09:46:43

AEID	
Adverse event	RUNNY NOSE
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)*	7 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)*	15 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	

FDA-CBER-2022-1614-3177867

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **29 Apr 2021 22:28:36**
Generated On: 10 Jun 2021 09:46:43

AEID	
Adverse event	SORE THROAT
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)*	7 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)*	13 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	

FDA-CBER-2022-1614-3177869

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **12 Feb 2021 19:04:09**
Generated On: 10 Jun 2021 09:46:43

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-3177871

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ■
Indication	TYPE II DIABETES MELLITUS
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177872

	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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	FENOFIBRATE
Prophylaxis	Yes ☐ No ■
Indication	HYPERLIPIDEMIA
Dose per administration	160
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 ☐

FDA-CBER-2022-1614-3177874

	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 2018
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	ROSUVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERLIPIDEMIA
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177876

	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 2018
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	LEXAPRO
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
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 ☐

FDA-CBER-2022-1614-3177878

	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 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	AZELASTINE
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	137
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 ☐

FDA-CBER-2022-1614-3177880

	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 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	ALBUTEROL HFA
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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 ☐

FDA-CBER-2022-1614-3177882

	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 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	CINNAMON
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177884

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	NIACIN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
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 ☐

FDA-CBER-2022-1614-3177886

	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 2017
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

Name of Medication	CURCUMIN WITH PEPPER
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177888

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	OMEGA 3 COMPLEX (FISH OIL)
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	3000
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 ☐

FDA-CBER-2022-1614-3177890

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	FEXOFENADINE
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	180
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177892

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	ZYRTEC
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177894

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
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 ☐

FDA-CBER-2022-1614-3177896

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	MELOXICAM
Prophylaxis	Yes ☐ No ■
Indication	JOINT PAIN (TYPE AND LOCATON UNKNOWN)
Dose per administration	15
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-3177898

	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 2017
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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
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 (16)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	TENDINITIS BILATERAL WRISTS
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)*	01 OCT 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	SEASONAL INFLUENZA VACCINATION
Prophylaxis	Yes ■ No ☐
Indication	PREVENTION OF SEASONAL 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 ☐

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	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)*	20 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	20 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	CORTICOSTEROID INJECTION BILATERAL WRISTS
Prophylaxis	Yes ☐ No ■
Indication	TENDINITIS BILATERAL WRISTS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	INJECTION
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	INTRAARTICULAR
Start date *(dd MMM yyyy)*	06 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	06 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

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

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	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)*	8 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	VALACYCLOVIR
Prophylaxis	Yes ☐ No ■
Indication	TREATMENT OF BELL'S PALSY
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 ☐

FDA-CBER-2022-1614-3177910

	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)*	8 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	18 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	MEDROL
Prophylaxis	Yes ☐ No ■
Indication	TREATMENT OF BELL'S PALSY
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)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 NOV 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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	LOVENOX
Prophylaxis	Yes ■ No ☐
Indication	STROKE PREVENTION
Dose per administration	UNKNOWN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN AT THIS TIME
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ■ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ■
If route of administration is Other, specify	UNKNOWN
Start date *(dd MMM yyyy)*	06 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	07 NOV 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	ADVIL + TYLENOL COMBO
Prophylaxis	Yes ☐ No ■
Indication	GENERAL PAIN RELIEF
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)*	UN UNK 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)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	NUTRAVESTA PROVEN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
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 ☐

FDA-CBER-2022-1614-3177918

	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 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 ■

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

	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 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 ■

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	TURMERIC
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
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)*	UN UNK 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

Name of Medication	PREDNISONE PACK
Prophylaxis	Yes ☐ No ■
Indication	TREATMENT OF BELL'S PALSY
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	6 DAY TAPER
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 NOV 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	PSEUDOEPHEDRINE HCL
Prophylaxis	Yes ☐ No ■
Indication	NASAL CONGESTION
Dose per administration	30
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 ☐

FDA-CBER-2022-1614-3177926

	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)*	10 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 DEC 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 ☐

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Name of Medication	LOW DOSE ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	THROMBOLYTIC PROPHYLAXIS
Dose per administration	81
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	2X WEEKLY
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3177928

	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)*	22 MAR 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 ☐

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **12 Feb 2021 19:04:09**
Generated On: 10 Jun 2021 09:46:43

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-3177930

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **31 Mar 2021 14:20:09**
Generated On: 10 Jun 2021 09:46:43

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
06 NOV 2020	CT W/O CONTRAST	Diagnostic	
06 NOV 2020	CHEST X-RAY	Adverse Event	
06 NOV 2020	MRI	Adverse Event	
25 MAR 2021	MRI W/ CONTRAST	Adverse Event	
25 MAR 2021	MRI W/O CONTRAST	Adverse Event	
15 MAR 2021	CAROTID ARTERY DOPPLER	Adverse Event	

FDA-CBER-2022-1614-3177931

US3752245
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:46:43

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

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 ☐

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

FDA-CBER-2022-1614-3177934

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (1)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	09/NOV/2020 09:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177935

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (2)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/NOV/2020 13:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177936

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (3)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	14/DEC/2020 11:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177937

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (4)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/JAN/2021 18:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177938

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (5)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	14/JAN/2021 12:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177939

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (6)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/FEB/2021 08:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177940

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (7)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177941

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (8)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/APR/2021 12:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177942

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (9)
Data signed: (b) (4) **23 Apr 2021 23:36:26**
Generated On: 10 Jun 2021 09:46:43

SAEID	USA-US113-2020-MRNA-1273-P301000009
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/APR/2021 12:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3177943

Audit

US3752245 (Prod: Baptist Health Center for Clinical Research)

US3752245
Form: Participant Creation
Generated On: 10 Jun 2021 09:46:43
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'US3752245'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:59:35

FDA-CBER-2022-1614-3177945

US3752245
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:57:13

US3752245
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:59:36

FDA-CBER-2022-1614-3177947

US3752245
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:57:13

FDA-CBER-2022-1614-3177948

US3752245
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'SCRN'	System	25 Aug 2020 19:57:13

FDA-CBER-2022-1614-3177949

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:59:37

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '67'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'YEARS'	System	26 Aug 2020 18:06:46

FDA-CBER-2022-1614-3177952

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '67'	System	25 Aug 2020 19:58:02

FDA-CBER-2022-1614-3177953

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:46:43
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:02

FDA-CBER-2022-1614-3177965

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Aug 2020'	System	25 Aug 2020 19:58:02

FDA-CBER-2022-1614-3177966

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2020'	System	25 Aug 2020 19:58:02

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US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:02

FDA-CBER-2022-1614-3177971

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:02

FDA-CBER-2022-1614-3177972

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:59:36

FDA-CBER-2022-1614-3177973

US3752245
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:46:43
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1'	System	25 Aug 2020 19:58:09

FDA-CBER-2022-1614-3177974

US3752245
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:46:43
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:58:09

US3752245
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:46:43
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User closed query 'Per Safety: Does the subject have a past medical history of Herpes Simplex Virus infection, Lyme, Epstein Barr Virus, Cytomegalovirus, or other viruses? If so, when was it diagnosed? If Yes, please add to medical history.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:36:08
User closed query ' Per Safety: Does the subject have a history of Bell's Palsy prior to enrollment? If yes, please add to medical history.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:35:59
Query 'Per Safety: Does the subject have a past medical history of Herpes Simplex Virus infection, Lyme, Epstein Barr Virus, Cytomegalovirus, or other viruses? If so, when was it diagnosed? If Yes, please add to medical history.' answered with 'no' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:17:30
Query ' Per Safety: Does the subject have a history of Bell's Palsy prior to enrollment? If yes, please add to medical history.' answered with 'no' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:17:16
User opened query 'Per Safety: Does the subject have a past medical history of Herpes Simplex Virus infection, Lyme, Epstein Barr Virus, Cytomegalovirus, or other viruses? If so, when was it diagnosed? If Yes, please add to medical history.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:01:21
User opened query ' Per Safety: Does the subject have a history of Bell's Palsy prior to enrollment? If yes, please add to medical history.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:01:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:10

FDA-CBER-2022-1614-3177976

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:18
Data point term sent to Coder	System	26 Aug 2020 18:07:30
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:29

FDA-CBER-2022-1614-3177978

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:29

FDA-CBER-2022-1614-3177980

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4), (b) (6) (b) (4)	26 Aug 2020 18:07:29

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2018'	System	26 Aug 2020 18:07:29

FDA-CBER-2022-1614-3177983

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2018'	System	26 Aug 2020 18:07:29

FDA-CBER-2022-1614-3177984

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:07:29

FDA-CBER-2022-1614-3177985

US3752245
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:07:29

FDA-CBER-2022-1614-3177986

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:36
Data point term sent to Coder	System	26 Aug 2020 18:08:31
User entered 'Asthma'	(b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:59

FDA-CBER-2022-1614-3177988

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:59

FDA-CBER-2022-1614-3177991

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2018'	System	26 Aug 2020 18:07:59

FDA-CBER-2022-1614-3177993

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2018'	System	26 Aug 2020 18:07:59

FDA-CBER-2022-1614-3177994

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:07:59

FDA-CBER-2022-1614-3177995

US3752245
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:07:59

FDA-CBER-2022-1614-3177996

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:35
Data point term sent to Coder	System	26 Aug 2020 18:08:31
User entered 'Diabetes mellitus type II'	(b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:08:14

FDA-CBER-2022-1614-3177998

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2017'	System	26 Aug 2020 18:08:14

FDA-CBER-2022-1614-3178003

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2017'	System	26 Aug 2020 18:08:14

FDA-CBER-2022-1614-3178004

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:08:14

US3752245
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:08:14

FDA-CBER-2022-1614-3178006

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:40
Data point term sent to Coder	System	26 Aug 2020 18:09:32
User entered 'Urinary incontinence'	(b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Aug 2020 18:08:39

FDA-CBER-2022-1614-3178008

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2004'	System	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2004'	System	26 Aug 2020 18:08:39

FDA-CBER-2022-1614-3178014

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:08:39

US3752245
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:08:39

FDA-CBER-2022-1614-3178016

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
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)	27 Aug 2020 17:59:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:38
Data point term sent to Coder	System	26 Aug 2020 18:09:35
User entered 'Depression'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2010'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

FDA-CBER-2022-1614-3178018

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2010'	System	26 Aug 2020 18:09:07

FDA-CBER-2022-1614-3178023

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2010'	System	26 Aug 2020 18:09:07

FDA-CBER-2022-1614-3178024

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:07

FDA-CBER-2022-1614-3178025

US3752245
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:07

FDA-CBER-2022-1614-3178026

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:39
Data point term sent to Coder	System	26 Aug 2020 18:09:35
User entered 'Seasonal allergies'	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:31

FDA-CBER-2022-1614-3178034

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:31

US3752245
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:31

FDA-CBER-2022-1614-3178036

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:45
Data point term sent to Coder	System	26 Aug 2020 18:10:38
User entered 'Obstructive sleep apnea'	(b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:09:47

FDA-CBER-2022-1614-3178038

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2017'	System	26 Aug 2020 18:09:47

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2017'	System	26 Aug 2020 18:09:47

FDA-CBER-2022-1614-3178044

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:47

FDA-CBER-2022-1614-3178045

US3752245
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	26 Aug 2020 18:09:47

FDA-CBER-2022-1614-3178046

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:46
Data point term sent to Coder	System	26 Aug 2020 18:10:38
User entered 'Tubal ligation'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1979'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1979'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 1979'	System	26 Aug 2020 18:10:17

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1979'	System	26 Aug 2020 18:10:17

FDA-CBER-2022-1614-3178054

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 1979'	System	26 Aug 2020 18:10:17

FDA-CBER-2022-1614-3178055

US3752245
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1979'	System	26 Aug 2020 18:10:17

FDA-CBER-2022-1614-3178056

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:48
Data point term sent to Coder	System	26 Aug 2020 18:11:39
User entered 'Tonsillectomy'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1974'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

FDA-CBER-2022-1614-3178058

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	26 Aug 2020 18:10:46

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1974'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 1974'	System	26 Aug 2020 18:10:46

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1974'	System	26 Aug 2020 18:10:46

FDA-CBER-2022-1614-3178064

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 1974'	System	26 Aug 2020 18:10:46

FDA-CBER-2022-1614-3178065

US3752245
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1974'	System	26 Aug 2020 18:10:46

FDA-CBER-2022-1614-3178066

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:48
Data point term sent to Coder	System	26 Aug 2020 18:11:42
User entered 'Colonoscopy'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2003'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

FDA-CBER-2022-1614-3178068

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2003'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

FDA-CBER-2022-1614-3178071

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2003'	System	26 Aug 2020 18:11:02

FDA-CBER-2022-1614-3178073

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2003'	System	26 Aug 2020 18:11:02

FDA-CBER-2022-1614-3178074

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2003'	System	26 Aug 2020 18:11:02

FDA-CBER-2022-1614-3178075

US3752245
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2003'	System	26 Aug 2020 18:11:02

FDA-CBER-2022-1614-3178076

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:49
Data point term sent to Coder	System	26 Aug 2020 18:11:42
User entered 'Colonoscopy'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

FDA-CBER-2022-1614-3178078

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2017'	System	26 Aug 2020 18:11:18

FDA-CBER-2022-1614-3178083

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2017'	System	26 Aug 2020 18:11:18

FDA-CBER-2022-1614-3178084

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2017'	System	26 Aug 2020 18:11:18

FDA-CBER-2022-1614-3178085

US3752245
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2017'	System	26 Aug 2020 18:11:18

FDA-CBER-2022-1614-3178086

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:52
Data point term sent to Coder	System	05 Nov 2020 15:08:38
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 15:07:53
User entered 'BREAST BIOPSY (unknown if benign or malignant)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:07:53
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:00:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:00:07
Data point term sent to Coder	System	26 Aug 2020 18:11:43
User entered 'Breast biopsy'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1994'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

FDA-CBER-2022-1614-3178088

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	26 Aug 2020 18:11:40

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1994'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 1994'	System	26 Aug 2020 18:11:40

FDA-CBER-2022-1614-3178093

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1994'	System	26 Aug 2020 18:11:40

FDA-CBER-2022-1614-3178094

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 1994'	System	26 Aug 2020 18:11:40

FDA-CBER-2022-1614-3178095

US3752245
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '1994'	System	26 Aug 2020 18:11:40

FDA-CBER-2022-1614-3178096

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:58:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:58:29
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:52
Data point term sent to Coder	System	05 Nov 2020 15:08:39
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 15:08:07
User entered 'BREAST BIOPSY (unknown if benign or malignant)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:08:07
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:52
Data point term sent to Coder	System	26 Aug 2020 18:12:46
User entered 'Breast biopsy'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

FDA-CBER-2022-1614-3178098

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2004'	System	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2004'	System	26 Aug 2020 18:11:57

FDA-CBER-2022-1614-3178104

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2004'	System	26 Aug 2020 18:11:57

US3752245
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2004'	System	26 Aug 2020 18:11:57

FDA-CBER-2022-1614-3178106

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:59:53
Data point term sent to Coder	System	26 Aug 2020 18:12:46
User entered 'Appendectomy'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2017'	System	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2017'	System	26 Aug 2020 18:12:14

FDA-CBER-2022-1614-3178114

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jan 2017'	System	26 Aug 2020 18:12:14

US3752245
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2017'	System	26 Aug 2020 18:12:14

FDA-CBER-2022-1614-3178116

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User closed query 'Per DM CLR: Please specify the location of JOINT PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:14:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 09:21:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 09:21:03
Data point term sent to Coder	System	29 Oct 2020 13:24:02
Query 'Per DM CLR: Please specify the location of JOINT PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:23:38
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 13:23:31
User entered 'JOINT PAIN (location and associated medical condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 13:23:31
User opened query 'Per DM CLR: Please specify the location of JOINT PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:02:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:14:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:14:37

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Sep 2020 16:14:14
User entered 'Joint pain'	(b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	29 Sep 2020 16:13:16

FDA-CBER-2022-1614-3178124

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	29 Sep 2020 16:13:16

FDA-CBER-2022-1614-3178125

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	29 Sep 2020 16:13:16

FDA-CBER-2022-1614-3178126

US3752245
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	29 Sep 2020 16:13:16

FDA-CBER-2022-1614-3178127

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:21:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:21:56
Data point term sent to Coder	System	07 Oct 2020 14:07:39
User entered 'Tendinitis bilateral wrists'	(b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:07:26

FDA-CBER-2022-1614-3178129

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:07:26

FDA-CBER-2022-1614-3178131

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'Jul 2020'	System	07 Oct 2020 14:07:26

FDA-CBER-2022-1614-3178134

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '2020'	System	07 Oct 2020 14:07:26

FDA-CBER-2022-1614-3178135

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	07 Oct 2020 14:07:26

FDA-CBER-2022-1614-3178136

US3752245
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	07 Oct 2020 14:07:26

FDA-CBER-2022-1614-3178137

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
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)	07 Oct 2020 15:14:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:14:58
Data point term sent to Coder	System	07 Oct 2020 14:08:41
User entered 'Penicillin allergy'	(b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178139

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '1'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178140

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178141

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178144

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178145

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178146

US3752245
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	07 Oct 2020 14:08:17

FDA-CBER-2022-1614-3178147

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
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)	10 Nov 2020 17:03:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:40
Data point term sent to Coder	System	10 Nov 2020 17:03:13
User entered 'NAPROXEN ALLERGY'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178149

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178150

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178151

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178152

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178154

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178155

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178156

US3752245
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:29

FDA-CBER-2022-1614-3178157

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:40
Data point term sent to Coder	System	10 Nov 2020 17:03:15
User entered 'LATEX ALLERGY'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178159

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178161

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178162

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178164

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178165

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178166

US3752245
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:02:52

FDA-CBER-2022-1614-3178167

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:01:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:01:55
User closed query 'Per MM, please expand the abbrevation ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:31:21
Query 'Per MM, please expand the abbrevation ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:45:49
Data point term sent to Coder	System	02 Dec 2020 14:45:46
Coding entries removed.	(b) (4), (b) (6)	02 Dec 2020 14:45:39
User entered 'PREVIOUS Cerebrovascular accident' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 14:45:39
User opened query 'Per MM, please expand the abbrevation ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 20:48:58
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 11:37:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 11:37:42
Data point term sent to Coder	System	10 Nov 2020 17:05:17
User entered 'PREVIOUS CVA'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178168

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178169

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178170

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178172

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178174

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178175

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178176

US3752245
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:46:43
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered empty.	System	10 Nov 2020 17:04:21

FDA-CBER-2022-1614-3178177

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '13:24'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:56

FDA-CBER-2022-1614-3178180

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered '25 Aug 2020 13:24'	System	26 Aug 2020 18:12:56

FDA-CBER-2022-1614-3178181

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '162.0' cm	(b) (4), (b) (6) (b) (4)	26 Aug 2020 18:12:56
DataPoint set to visible.	System	25 Aug 2020 19:58:09

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '95.4' kg	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:56
DataPoint set to visible.	System	25 Aug 2020 19:58:09

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
Amendment Manager: User entered '36.35117'	System	17 Sep 2020 00:02:17
User entered '36.4'	System	26 Aug 2020 18:12:56
DataPoint set to visible.	System	25 Aug 2020 19:58:09

FDA-CBER-2022-1614-3178184

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'kg/m2'	System	26 Aug 2020 18:12:56
DataPoint set to visible.	System	25 Aug 2020 19:58:09

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'bpm'	System	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'breaths/min'	System	26 Aug 2020 18:12:56

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US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'mmHg'	System	26 Aug 2020 18:12:56

FDA-CBER-2022-1614-3178194

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User entered 'mmHg'	System	26 Aug 2020 18:12:56

FDA-CBER-2022-1614-3178196

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50

FDA-CBER-2022-1614-3178197

US3752245
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50

FDA-CBER-2022-1614-3178198

US3752245
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:21:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 19:50:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:41:07
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:13:16

US3752245
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:21:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 19:50:46
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:41:07
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:13:16

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 05:00:13
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 15:45:53
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Tubal ligation noted in MH' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:45:42
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 15:45:28
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:45:28
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 04:36:38
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'un UNK 1979' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:45:28
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:14:19

FDA-CBER-2022-1614-3178207

US3752245
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:46:43
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:45:53
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:46:43
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:15:45

US3752245
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:15:45

FDA-CBER-2022-1614-3178231

US3752245
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 18:15:45

US3752245
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'VISIT1'	System	26 Aug 2020 18:15:45

FDA-CBER-2022-1614-3178233

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 19:14:43

FDA-CBER-2022-1614-3178234

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '188125'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 19:14:43

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 19:14:43

FDA-CBER-2022-1614-3178236

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:16:22
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

FDA-CBER-2022-1614-3178240

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

FDA-CBER-2022-1614-3178241

US3752245
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:46:43
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 14:03:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:53:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:52:59

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:46:43
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178243

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:46:43
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178244

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:46:43
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:46:43
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178246

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178247

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178248

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '13:24'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178250

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '25 Aug 2020 13:24'	System	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178251

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '97.8' F	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:17:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:17:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:17:17
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:17:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:17:17
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:17:17
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'bpm'	System	26 Aug 2020 18:17:17
User entered empty.	System	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:17:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:17:17
User entered '19' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:17:17
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'breaths/min'	System	26 Aug 2020 18:17:17
User entered empty.	System	26 Aug 2020 18:16:56

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US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:17:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:17:17
User entered '138' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:17:17
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	26 Aug 2020 18:17:17
User entered empty.	System	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178260

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:17:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:17:17
User entered '080' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:17:17
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	26 Aug 2020 18:17:17
User entered empty.	System	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:46:43
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178263

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:46:43
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178265

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178266

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:08
User entered '15:10' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '25 Aug 2020 15:10'	System	26 Aug 2020 18:18:08
User entered empty.	System	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Aug 2020 18:18:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:08
User entered '98.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:13
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:13
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:13
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:08
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:08
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'bpm'	System	26 Aug 2020 18:18:08
User entered empty.	System	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178274

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:08
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'breaths/min'	System	26 Aug 2020 18:18:08
User entered empty.	System	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178276

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:08
User entered '124' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	26 Aug 2020 18:18:08
User entered empty.	System	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178278

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:18:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Aug 2020 18:18:08
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:16:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	26 Aug 2020 18:18:08
User entered empty.	System	26 Aug 2020 18:16:56

FDA-CBER-2022-1614-3178280

US3752245
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:41:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:18:26

US3752245
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:41:21
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:18:26

FDA-CBER-2022-1614-3178282

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178283

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178284

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178286

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178287

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '14:37'	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '25 Aug 2020 14:37'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178289

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'ONCE'	System	25 Aug 2020 19:59:00

US3752245
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 19:59:00

US3752245
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:18:56

US3752245
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:18:56

FDA-CBER-2022-1614-3178294

US3752245
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '13:44'	(b) (4), (b) (6)	26 Aug 2020 18:18:56

FDA-CBER-2022-1614-3178295

US3752245
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '25 Aug 2020 13:44'	System	26 Aug 2020 18:18:56

FDA-CBER-2022-1614-3178296

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '13:41'	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '25 Aug 2020 13:41'	System	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered empty.	System	26 Aug 2020 18:19:10

US3752245
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:19:18

US3752245
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	26 Aug 2020 18:19:18

FDA-CBER-2022-1614-3178307

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:08', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '20b7cef0-ea13-4027-8e54-f9baddbcfad7'	System	25 Aug 2020 20:01:37
User entered 'Yes (Y)'	System	25 Aug 2020 20:01:37

FDA-CBER-2022-1614-3178309

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:18', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '20b7cef0-ea13-4027-8e54-f9baddbcfad7'	System	25 Aug 2020 20:01:37
User entered '98.9'	System	25 Aug 2020 20:01:37

FDA-CBER-2022-1614-3178310

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:26', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '20b7cef0-ea13-4027-8e54-f9baddbcfad7'	System	25 Aug 2020 20:01:37
User entered 'No (N)'	System	25 Aug 2020 20:01:37

FDA-CBER-2022-1614-3178311

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:34', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '20b7cef0-ea13-4027-8e54-f9baddbcfad7'	System	25 Aug 2020 20:01:37
User entered '25 Aug 2020 15:01'	System	25 Aug 2020 20:01:37

FDA-CBER-2022-1614-3178312

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 14:57'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178313

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178314

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:14', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '402f415e-b0d2-4f23-8a19-6d32ac2e99c3'	System	26 Aug 2020 11:03:40
User entered 'Yes (Y)'	System	26 Aug 2020 11:03:40

FDA-CBER-2022-1614-3178316

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:22', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '402f415e-b0d2-4f23-8a19-6d32ac2e99c3'	System	26 Aug 2020 11:03:40
User entered '97.3'	System	26 Aug 2020 11:03:40

FDA-CBER-2022-1614-3178317

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:30', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '402f415e-b0d2-4f23-8a19-6d32ac2e99c3'	System	26 Aug 2020 11:03:40
User entered 'No (N)'	System	26 Aug 2020 11:03:40

FDA-CBER-2022-1614-3178318

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:37', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '402f415e-b0d2-4f23-8a19-6d32ac2e99c3'	System	26 Aug 2020 11:03:40
User entered '26 Aug 2020 06:03'	System	26 Aug 2020 11:03:40

FDA-CBER-2022-1614-3178319

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 18:22'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178320

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178321

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 2'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178322

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b5bd7921-d6f6-4abe-a3e4-40d758b4c930'	System	26 Aug 2020 17:55:22
User entered 'Yes (Y)'	System	26 Aug 2020 17:55:22

FDA-CBER-2022-1614-3178323

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:09', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b5bd7921-d6f6-4abe-a3e4-40d758b4c930'	System	26 Aug 2020 17:55:22
User entered '97.4'	System	26 Aug 2020 17:55:22

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:14', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b5bd7921-d6f6-4abe-a3e4-40d758b4c930'	System	26 Aug 2020 17:55:22
User entered 'No (N)'	System	26 Aug 2020 17:55:22

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:19', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b5bd7921-d6f6-4abe-a3e4-40d758b4c930'	System	26 Aug 2020 17:55:22
User entered '26 Aug 2020 12:55'	System	26 Aug 2020 17:55:22

FDA-CBER-2022-1614-3178326

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178327

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178328

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 3'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178329

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd458247d-efa7-4e8b-a8f4-0fcdc63c4dc6'	System	27 Aug 2020 19:24:36
User entered 'Yes (Y)'	System	27 Aug 2020 19:24:36

FDA-CBER-2022-1614-3178330

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:08', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd458247d-efa7-4e8b-a8f4-0fcdc63c4dc6'	System	27 Aug 2020 19:24:36
User entered '97.7'	System	27 Aug 2020 19:24:36

FDA-CBER-2022-1614-3178331

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:11', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd458247d-efa7-4e8b-a8f4-0fcdc63c4dc6'	System	27 Aug 2020 19:24:36
User entered 'No (N)'	System	27 Aug 2020 19:24:36

FDA-CBER-2022-1614-3178332

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:16', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd458247d-efa7-4e8b-a8f4-0fcdc63c4dc6'	System	27 Aug 2020 19:24:36
User entered '27 Aug 2020 14:24'	System	27 Aug 2020 19:24:36

FDA-CBER-2022-1614-3178333

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178334

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178335

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 4'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178336

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:26', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '44541264-60fe-4d17-ac2a-3157c55e829f'	System	29 Aug 2020 01:59:43
User entered 'Yes (Y)'	System	29 Aug 2020 01:59:43

FDA-CBER-2022-1614-3178337

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '44541264-60fe-4d17-ac2a-3157c55e829f'	System	29 Aug 2020 01:59:43
User entered '97.6'	System	29 Aug 2020 01:59:43

FDA-CBER-2022-1614-3178338

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:36', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '44541264-60fe-4d17-ac2a-3157c55e829f'	System	29 Aug 2020 01:59:43
User entered 'No (N)'	System	29 Aug 2020 01:59:43

FDA-CBER-2022-1614-3178339

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:40', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '44541264-60fe-4d17-ac2a-3157c55e829f'	System	29 Aug 2020 01:59:43
User entered '28 Aug 2020 20:59'	System	29 Aug 2020 01:59:43

FDA-CBER-2022-1614-3178340

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178341

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178342

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 5'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:51:50', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '7ad1e67e-842d-4e62-bccd-f973e98d22be'	System	29 Aug 2020 19:52:11
User entered 'Yes (Y)'	System	29 Aug 2020 19:52:11

FDA-CBER-2022-1614-3178344

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '7ad1e67e-842d-4e62-bccd-f973e98d22be'	System	29 Aug 2020 19:52:11
User entered '97.3'	System	29 Aug 2020 19:52:11

FDA-CBER-2022-1614-3178345

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '7ad1e67e-842d-4e62-bccd-f973e98d22be'	System	29 Aug 2020 19:52:11
User entered 'No (N)'	System	29 Aug 2020 19:52:11

FDA-CBER-2022-1614-3178346

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:07', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '7ad1e67e-842d-4e62-bccd-f973e98d22be'	System	29 Aug 2020 19:52:11
User entered '29 Aug 2020 14:52'	System	29 Aug 2020 19:52:11

FDA-CBER-2022-1614-3178347

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178348

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178349

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 6'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:01:14', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e4fef94c-5f7e-4579-bfda-a76c55797698'	System	30 Aug 2020 17:01:57
User entered 'Yes (Y)'	System	30 Aug 2020 17:01:57

FDA-CBER-2022-1614-3178351

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:01:36', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e4fef94c-5f7e-4579-bfda-a76c55797698'	System	30 Aug 2020 17:01:57
User entered '97.4'	System	30 Aug 2020 17:01:57

FDA-CBER-2022-1614-3178352

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:01:44', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e4fef94c-5f7e-4579-bfda-a76c55797698'	System	30 Aug 2020 17:01:57
User entered 'No (N)'	System	30 Aug 2020 17:01:57

FDA-CBER-2022-1614-3178353

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:01:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e4fef94c-5f7e-4579-bfda-a76c55797698'	System	30 Aug 2020 17:01:57
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:57

FDA-CBER-2022-1614-3178354

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178355

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178356

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 7'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:29', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14aff5f1-0d9c-44f9-8a8d-2103fc67a39d'	System	31 Aug 2020 20:27:21
User entered 'Yes (Y)'	System	31 Aug 2020 20:27:21

FDA-CBER-2022-1614-3178358

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:37', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14aff5f1-0d9c-44f9-8a8d-2103fc67a39d'	System	31 Aug 2020 20:27:21
User entered '97.4'	System	31 Aug 2020 20:27:21

FDA-CBER-2022-1614-3178359

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:40', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14aff5f1-0d9c-44f9-8a8d-2103fc67a39d'	System	31 Aug 2020 20:27:21
User entered 'No (N)'	System	31 Aug 2020 20:27:21

FDA-CBER-2022-1614-3178360

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:43', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14aff5f1-0d9c-44f9-8a8d-2103fc67a39d'	System	31 Aug 2020 20:27:21
User entered '31 Aug 2020 15:25'	System	31 Aug 2020 20:27:21

FDA-CBER-2022-1614-3178361

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178362

US3752245
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178363

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:45', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14456bf1-8851-4875-a590-842c8520b946'	System	25 Aug 2020 20:02:28
User entered 'None (1)'	System	25 Aug 2020 20:02:28

FDA-CBER-2022-1614-3178365

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:50', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14456bf1-8851-4875-a590-842c8520b946'	System	25 Aug 2020 20:02:28
User entered 'No (N)'	System	25 Aug 2020 20:02:28

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:01:56', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14456bf1-8851-4875-a590-842c8520b946'	System	25 Aug 2020 20:02:28
User entered 'No (N)'	System	25 Aug 2020 20:02:28

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:09', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14456bf1-8851-4875-a590-842c8520b946'	System	25 Aug 2020 20:02:28
User entered 'None (1)'	System	25 Aug 2020 20:02:28

FDA-CBER-2022-1614-3178368

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:18', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '14456bf1-8851-4875-a590-842c8520b946'	System	25 Aug 2020 20:02:28
User entered '25 Aug 2020 15:02'	System	25 Aug 2020 20:02:28

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 14:57'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178370

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178371

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '59dde0db-cda2-4453-99e7-567ffc35f7d4'	System	26 Aug 2020 11:04:28
User entered 'None (1)'	System	26 Aug 2020 11:04:28

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:50', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '59dde0db-cda2-4453-99e7-567ffc35f7d4'	System	26 Aug 2020 11:04:28
User entered 'No (N)'	System	26 Aug 2020 11:04:28

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:03:56', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '59dde0db-cda2-4453-99e7-567ffc35f7d4'	System	26 Aug 2020 11:04:28
User entered 'No (N)'	System	26 Aug 2020 11:04:28

FDA-CBER-2022-1614-3178375

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '59dde0db-cda2-4453-99e7-567ffc35f7d4'	System	26 Aug 2020 11:04:28
User entered 'None (1)'	System	26 Aug 2020 11:04:28

FDA-CBER-2022-1614-3178376

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:24', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '59dde0db-cda2-4453-99e7-567ffc35f7d4'	System	26 Aug 2020 11:04:28
User entered '26 Aug 2020 06:04'	System	26 Aug 2020 11:04:28

FDA-CBER-2022-1614-3178377

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 18:22'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178378

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178379

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 2'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178380

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:24', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '40c73bd3-1dcd-4aa8-986f-03283667544f'	System	26 Aug 2020 17:55:54
User entered 'None (1)'	System	26 Aug 2020 17:55:54

FDA-CBER-2022-1614-3178381

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:27', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '40c73bd3-1dcd-4aa8-986f-03283667544f'	System	26 Aug 2020 17:55:54
User entered 'No (N)'	System	26 Aug 2020 17:55:54

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:31', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '40c73bd3-1dcd-4aa8-986f-03283667544f'	System	26 Aug 2020 17:55:54
User entered 'No (N)'	System	26 Aug 2020 17:55:54

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:37', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '40c73bd3-1dcd-4aa8-986f-03283667544f'	System	26 Aug 2020 17:55:54
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 17:55:54

FDA-CBER-2022-1614-3178384

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:50', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '40c73bd3-1dcd-4aa8-986f-03283667544f'	System	26 Aug 2020 17:55:54
User entered '26 Aug 2020 12:55'	System	26 Aug 2020 17:55:54

FDA-CBER-2022-1614-3178385

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178386

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178387

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 3'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178388

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:22', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ab585d16-3b2a-4eb4-907f-863387397db7'	System	27 Aug 2020 19:24:39
User entered 'None (1)'	System	27 Aug 2020 19:24:39

FDA-CBER-2022-1614-3178389

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ab585d16-3b2a-4eb4-907f-863387397db7'	System	27 Aug 2020 19:24:39
User entered 'No (N)'	System	27 Aug 2020 19:24:39

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:29', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ab585d16-3b2a-4eb4-907f-863387397db7'	System	27 Aug 2020 19:24:39
User entered 'No (N)'	System	27 Aug 2020 19:24:39

FDA-CBER-2022-1614-3178391

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ab585d16-3b2a-4eb4-907f-863387397db7'	System	27 Aug 2020 19:24:39
User entered 'None (1)'	System	27 Aug 2020 19:24:39

FDA-CBER-2022-1614-3178392

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:37', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ab585d16-3b2a-4eb4-907f-863387397db7'	System	27 Aug 2020 19:24:39
User entered '27 Aug 2020 14:24'	System	27 Aug 2020 19:24:39

FDA-CBER-2022-1614-3178393

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178394

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178395

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 4'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178396

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '043e839b-e8b4-4e8b-84cb-b8f38c610fa4'	System	29 Aug 2020 02:00:12
User entered 'None (1)'	System	29 Aug 2020 02:00:12

FDA-CBER-2022-1614-3178397

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:50', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '043e839b-e8b4-4e8b-84cb-b8f38c610fa4'	System	29 Aug 2020 02:00:12
User entered 'No (N)'	System	29 Aug 2020 02:00:12

FDA-CBER-2022-1614-3178398

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:54', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '043e839b-e8b4-4e8b-84cb-b8f38c610fa4'	System	29 Aug 2020 02:00:12
User entered 'No (N)'	System	29 Aug 2020 02:00:12

FDA-CBER-2022-1614-3178399

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T20:59:58', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '043e839b-e8b4-4e8b-84cb-b8f38c610fa4'	System	29 Aug 2020 02:00:12
User entered 'None (1)'	System	29 Aug 2020 02:00:12

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '043e839b-e8b4-4e8b-84cb-b8f38c610fa4'	System	29 Aug 2020 02:00:12
User entered '28 Aug 2020 21:00'	System	29 Aug 2020 02:00:12

FDA-CBER-2022-1614-3178401

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178402

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178403

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 5'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178404

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:11', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'f80e157b-7477-4c61-93ec-e0d8e378e740'	System	29 Aug 2020 19:52:28
User entered 'None (1)'	System	29 Aug 2020 19:52:28

FDA-CBER-2022-1614-3178405

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:15', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'f80e157b-7477-4c61-93ec-e0d8e378e740'	System	29 Aug 2020 19:52:28
User entered 'No (N)'	System	29 Aug 2020 19:52:28

FDA-CBER-2022-1614-3178406

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:19', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'f80e157b-7477-4c61-93ec-e0d8e378e740'	System	29 Aug 2020 19:52:28
User entered 'No (N)'	System	29 Aug 2020 19:52:28

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'f80e157b-7477-4c61-93ec-e0d8e378e740'	System	29 Aug 2020 19:52:28
User entered 'None (1)'	System	29 Aug 2020 19:52:28

FDA-CBER-2022-1614-3178408

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:24', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'f80e157b-7477-4c61-93ec-e0d8e378e740'	System	29 Aug 2020 19:52:28
User entered '29 Aug 2020 14:52'	System	29 Aug 2020 19:52:28

FDA-CBER-2022-1614-3178409

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178410

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178411

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 6'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178412

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:01:57', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '81ae5944-874f-491d-92d7-104a1b08d57d'	System	30 Aug 2020 17:02:22
User entered 'None (1)'	System	30 Aug 2020 17:02:22

FDA-CBER-2022-1614-3178413

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:01', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '81ae5944-874f-491d-92d7-104a1b08d57d'	System	30 Aug 2020 17:02:22
User entered 'No (N)'	System	30 Aug 2020 17:02:22

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:04', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '81ae5944-874f-491d-92d7-104a1b08d57d'	System	30 Aug 2020 17:02:22
User entered 'No (N)'	System	30 Aug 2020 17:02:22

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:12', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '81ae5944-874f-491d-92d7-104a1b08d57d'	System	30 Aug 2020 17:02:22
User entered 'None (1)'	System	30 Aug 2020 17:02:22

FDA-CBER-2022-1614-3178416

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:18', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '81ae5944-874f-491d-92d7-104a1b08d57d'	System	30 Aug 2020 17:02:22
User entered '30 Aug 2020 12:02'	System	30 Aug 2020 17:02:22

FDA-CBER-2022-1614-3178417

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178418

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178419

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 7'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178420

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:47', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd700cafa-e555-4819-822a-eba1b7727290'	System	31 Aug 2020 20:27:24
User entered 'None (1)'	System	31 Aug 2020 20:27:24

FDA-CBER-2022-1614-3178421

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:49', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd700cafa-e555-4819-822a-eba1b7727290'	System	31 Aug 2020 20:27:24
User entered 'No (N)'	System	31 Aug 2020 20:27:24

FDA-CBER-2022-1614-3178422

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd700cafa-e555-4819-822a-eba1b7727290'	System	31 Aug 2020 20:27:24
User entered 'No (N)'	System	31 Aug 2020 20:27:24

FDA-CBER-2022-1614-3178423

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:54', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd700cafa-e555-4819-822a-eba1b7727290'	System	31 Aug 2020 20:27:24
User entered 'None (1)'	System	31 Aug 2020 20:27:24

FDA-CBER-2022-1614-3178424

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:25:57', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd700cafa-e555-4819-822a-eba1b7727290'	System	31 Aug 2020 20:27:24
User entered '31 Aug 2020 15:25'	System	31 Aug 2020 20:27:24

FDA-CBER-2022-1614-3178425

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178426

US3752245
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178427

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178428

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'None (0)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178429

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:28', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'None (0)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178430

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'None (0)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178431

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:40', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'None (0)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178432

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:43', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'None (0)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178433

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'None (0)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178434

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:02:54', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered 'No (N)'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178435

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-25T15:03:01', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ccd260cf-c911-44f9-b401-8ff5581ba0f7'	System	25 Aug 2020 20:03:05
User entered '25 Aug 2020 15:03'	System	25 Aug 2020 20:03:05

FDA-CBER-2022-1614-3178436

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 14:57'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178437

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178438

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178439

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:30', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'None (0)'	System	26 Aug 2020 11:04:54

FDA-CBER-2022-1614-3178440

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'None (0)'	System	26 Aug 2020 11:04:54

FDA-CBER-2022-1614-3178441

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:36', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'None (0)'	System	26 Aug 2020 11:04:54

FDA-CBER-2022-1614-3178442

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'None (0)'	System	26 Aug 2020 11:04:54

FDA-CBER-2022-1614-3178443

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:41', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'None (0)'	System	26 Aug 2020 11:04:54

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:44', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'None (0)'	System	26 Aug 2020 11:04:54

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:48', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered 'No (N)'	System	26 Aug 2020 11:04:54

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T06:04:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90b3093b-006d-4e5e-990e-abf03f5f72fe'	System	26 Aug 2020 11:04:54
User entered '26 Aug 2020 06:04'	System	26 Aug 2020 11:04:54

FDA-CBER-2022-1614-3178447

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '25 Aug 2020 18:22'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178448

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178449

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 2'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178450

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:57', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'None (0)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178451

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:55:59', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'None (0)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178452

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:56:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'None (0)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178453

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:56:04', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'None (0)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178454

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:56:07', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'None (0)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178455

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:56:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'None (0)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178456

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:56:16', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered 'No (N)'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178457

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-26T12:56:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fcefaf96-e714-4fce-ae8f-f6a75503f469'	System	26 Aug 2020 17:56:26
User entered '26 Aug 2020 12:56'	System	26 Aug 2020 17:56:26

FDA-CBER-2022-1614-3178458

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178459

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178460

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 3'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178461

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:44', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'None (0)'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178462

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'None (0)'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178463

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:48', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'None (0)'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178464

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'None (0)'	System	27 Aug 2020 19:25:06

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:53', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'None (0)'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178466

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:24:55', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'None (0)'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178467

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:25:01', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered 'No (N)'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178468

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-27T14:25:04', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd95da33c-e39c-4019-a178-b851acbd62e2'	System	27 Aug 2020 19:25:06
User entered '27 Aug 2020 14:25'	System	27 Aug 2020 19:25:06

FDA-CBER-2022-1614-3178469

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178470

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178471

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 4'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178472

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:06', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'None (0)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178473

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:09', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'None (0)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178474

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:12', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'None (0)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178475

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:14', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'None (0)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178476

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:16', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'None (0)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178477

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:19', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'None (0)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178478

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:27', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered 'Yes (Y)'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178479

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-28T21:00:31', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '00139af4-a257-4d7a-beb4-3c27cd743b4e'	System	29 Aug 2020 02:00:35
User entered '28 Aug 2020 21:00'	System	29 Aug 2020 02:00:35

FDA-CBER-2022-1614-3178480

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178481

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178482

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 5'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178483

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:28', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'None (0)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178484

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:30', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'None (0)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178485

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:32', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'None (0)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178486

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:35', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'None (0)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178487

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'None (0)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178488

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:41', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'None (0)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178489

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:45', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered 'No (N)'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178490

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-29T14:52:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c7648a6e-0c55-4b3a-831c-af5f5a2cd400'	System	29 Aug 2020 19:52:56
User entered '29 Aug 2020 14:52'	System	29 Aug 2020 19:52:56

FDA-CBER-2022-1614-3178491

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178492

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178493

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 6'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178494

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:23', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'None (0)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178495

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'None (0)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178496

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:28', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'None (0)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178497

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:30', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'None (0)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178498

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'None (0)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178499

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:35', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'None (0)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178500

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered 'No (N)'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178501

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-30T12:02:42', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'af43956d-a5b7-4b14-99f8-611d3a669b13'	System	30 Aug 2020 17:02:47
User entered '30 Aug 2020 12:02'	System	30 Aug 2020 17:02:47

FDA-CBER-2022-1614-3178502

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178503

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178504

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 7'	System	25 Aug 2020 19:59:00

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:01', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'None (0)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178506

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'None (0)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178507

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:06', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'None (0)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178508

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'None (0)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178509

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:13', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'None (0)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178510

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:15', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'None (0)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178511

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:22', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered 'No (N)'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178512

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-08-31T15:26:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '1ad74ca4-b409-4a9a-8544-052ba075276e'	System	31 Aug 2020 20:27:29
User entered '31 Aug 2020 15:26'	System	31 Aug 2020 20:27:29

FDA-CBER-2022-1614-3178513

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178514

US3752245
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:02:21

US3752245
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:02:21

US3752245
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 14:02:21

FDA-CBER-2022-1614-3178518

US3752245
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:02:21

FDA-CBER-2022-1614-3178519

US3752245
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:00:02

US3752245
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	23 Sep 2020 14:00:02

US3752245
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:01:33

US3752245
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:01:33

US3752245
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 14:01:33

US3752245
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:01:33

FDA-CBER-2022-1614-3178525

US3752245
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:00:14

US3752245
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	23 Sep 2020 14:00:14

US3752245
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:00:39

US3752245
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:00:39

US3752245
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 14:00:39

US3752245
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:00:39

FDA-CBER-2022-1614-3178531

US3752245
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	Lauren Evans (b) (4)	06 Oct 2020 18:35:29

US3752245
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	06 Oct 2020 18:35:29

US3752245
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	Lauren Evans (b) (4)	06 Oct 2020 18:36:06

FDA-CBER-2022-1614-3178534

US3752245
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 20:21:37
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'dates confirmed' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 13:23:30
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Oct 2020 18:36:06
User entered '6 Oct 2020'	Lauren Evans (b) (4)	06 Oct 2020 18:36:06

US3752245
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Clinic (Clinic)'	Lauren Evans (b) (4)	06 Oct 2020 18:36:06

FDA-CBER-2022-1614-3178536

US3752245
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'VISIT2'	System	06 Oct 2020 18:36:06

FDA-CBER-2022-1614-3178537

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178539

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178540

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '12:40'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178541

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '06 Oct 2020 12:40'	System	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178542

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '99.2' F	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:09
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178544

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:09
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:09
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

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US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'bpm'	System	07 Oct 2020 14:04:09
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:09
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:09
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'breaths/min'	System	07 Oct 2020 14:04:09
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:09
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:09
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178550

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	07 Oct 2020 14:04:09
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:09
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:09
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	07 Oct 2020 14:04:09
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178554

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178556

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:59
User entered '13:45' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '06 Oct 2020 13:45'	System	07 Oct 2020 14:04:59
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:59
User entered '99.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178560

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178561

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:59
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'bpm'	System	07 Oct 2020 14:04:59
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:59
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'breaths/min'	System	07 Oct 2020 14:04:59
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:59
User entered '112' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178566

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	07 Oct 2020 14:04:59
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:04:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 14:04:59
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 14:04:59
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 14:03:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:03:46

FDA-CBER-2022-1614-3178568

US3752245
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	07 Oct 2020 14:04:59
User entered empty.	System	07 Oct 2020 14:03:46

US3752245
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:05:10

US3752245
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:05:10

FDA-CBER-2022-1614-3178571

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178573

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178574

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 18:36:45

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '6 Oct 2020'	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178576

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '13:30'	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178577

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '6 Oct 2020 13:30'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178578

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Left Arm (LEFT ARM)'	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'ONCE'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178580

US3752245
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:46:43
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178581

US3752245
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:05:39

FDA-CBER-2022-1614-3178582

US3752245
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:05:39

FDA-CBER-2022-1614-3178583

US3752245
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '12:59'	(b) (4), (b) (6)	07 Oct 2020 14:05:39

FDA-CBER-2022-1614-3178584

US3752245
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '06 Oct 2020 12:59'	System	07 Oct 2020 14:05:39

FDA-CBER-2022-1614-3178585

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:05:55

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 14:05:55

FDA-CBER-2022-1614-3178587

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:05:55

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '12:57'	(b) (4), (b) (6)	07 Oct 2020 14:05:55

FDA-CBER-2022-1614-3178589

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '06 Oct 2020 12:57'	System	07 Oct 2020 14:05:55

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 14:05:55

FDA-CBER-2022-1614-3178591

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 14:05:55

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:05:55

FDA-CBER-2022-1614-3178593

US3752245
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered empty.	System	07 Oct 2020 14:05:55

US3752245
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:06:00

US3752245
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	07 Oct 2020 14:06:00

FDA-CBER-2022-1614-3178596

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:14', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '99f979ab-00dd-4684-b2b3-25b57d19052c'	System	06 Oct 2020 18:52:05
User entered 'Yes (Y)'	System	06 Oct 2020 18:52:05

FDA-CBER-2022-1614-3178598

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '99f979ab-00dd-4684-b2b3-25b57d19052c'	System	06 Oct 2020 18:52:05
User entered '99.2'	System	06 Oct 2020 18:52:05

FDA-CBER-2022-1614-3178599

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:29', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '99f979ab-00dd-4684-b2b3-25b57d19052c'	System	06 Oct 2020 18:52:05
User entered 'No (N)'	System	06 Oct 2020 18:52:05

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:36', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '99f979ab-00dd-4684-b2b3-25b57d19052c'	System	06 Oct 2020 18:52:05
User entered '06 Oct 2020 13:51'	System	06 Oct 2020 18:52:05

FDA-CBER-2022-1614-3178601

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 13:50'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178602

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 16:20'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178603

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:08', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'be04af41-cd85-44a9-a40e-602551b07862'	System	06 Oct 2020 22:16:36
User entered 'Yes (Y)'	System	06 Oct 2020 22:16:36

FDA-CBER-2022-1614-3178605

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'be04af41-cd85-44a9-a40e-602551b07862'	System	06 Oct 2020 22:16:36
User entered '99.4'	System	06 Oct 2020 22:16:36

FDA-CBER-2022-1614-3178606

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:29', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'be04af41-cd85-44a9-a40e-602551b07862'	System	06 Oct 2020 22:16:36
User entered 'No (N)'	System	06 Oct 2020 22:16:36

FDA-CBER-2022-1614-3178607

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'be04af41-cd85-44a9-a40e-602551b07862'	System	06 Oct 2020 22:16:36
User entered '06 Oct 2020 17:16'	System	06 Oct 2020 22:16:36

FDA-CBER-2022-1614-3178608

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 17:15'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178609

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178610

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 2'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178611

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:00:48', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e3e26ec5-981a-46b5-b44e-666f4dcb6b18'	System	07 Oct 2020 18:01:51
User entered 'Yes (Y)'	System	07 Oct 2020 18:01:51

FDA-CBER-2022-1614-3178612

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:00:54', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e3e26ec5-981a-46b5-b44e-666f4dcb6b18'	System	07 Oct 2020 18:01:51
User entered '98.2'	System	07 Oct 2020 18:01:51

FDA-CBER-2022-1614-3178613

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:00:58', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e3e26ec5-981a-46b5-b44e-666f4dcb6b18'	System	07 Oct 2020 18:01:51
User entered 'No (N)'	System	07 Oct 2020 18:01:51

FDA-CBER-2022-1614-3178614

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:01:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e3e26ec5-981a-46b5-b44e-666f4dcb6b18'	System	07 Oct 2020 18:01:51
User entered '07 Oct 2020 13:01'	System	07 Oct 2020 18:01:51

FDA-CBER-2022-1614-3178615

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178616

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178617

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 3'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:03:34', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '4d86bd31-2616-4ec0-8e5a-ed8738d752b8'	System	09 Oct 2020 10:04:24
User entered 'Yes (Y)'	System	09 Oct 2020 10:04:24

FDA-CBER-2022-1614-3178619

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:04:09', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '4d86bd31-2616-4ec0-8e5a-ed8738d752b8'	System	09 Oct 2020 10:04:24
User entered '97.8'	System	09 Oct 2020 10:04:24

FDA-CBER-2022-1614-3178620

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:04:16', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '4d86bd31-2616-4ec0-8e5a-ed8738d752b8'	System	09 Oct 2020 10:04:24
User entered 'No (N)'	System	09 Oct 2020 10:04:24

FDA-CBER-2022-1614-3178621

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:04:19', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '4d86bd31-2616-4ec0-8e5a-ed8738d752b8'	System	09 Oct 2020 10:04:24
User entered '09 Oct 2020 05:04'	System	09 Oct 2020 10:04:24

FDA-CBER-2022-1614-3178622

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178623

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178624

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 4'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178625

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:00:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '658b8166-edc5-4abf-a37b-999da9676b69'	System	09 Oct 2020 17:00:55
User entered 'Yes (Y)'	System	09 Oct 2020 17:00:55

FDA-CBER-2022-1614-3178626

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:00:44', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '658b8166-edc5-4abf-a37b-999da9676b69'	System	09 Oct 2020 17:00:55
User entered '98.2'	System	09 Oct 2020 17:00:55

FDA-CBER-2022-1614-3178627

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:00:48', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '658b8166-edc5-4abf-a37b-999da9676b69'	System	09 Oct 2020 17:00:55
User entered 'No (N)'	System	09 Oct 2020 17:00:55

FDA-CBER-2022-1614-3178628

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:00:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '658b8166-edc5-4abf-a37b-999da9676b69'	System	09 Oct 2020 17:00:55
User entered '09 Oct 2020 12:00'	System	09 Oct 2020 17:00:55

FDA-CBER-2022-1614-3178629

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178630

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178631

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 5'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178632

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178633

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178634

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178635

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178636

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178637

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178638

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178639

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178640

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 6'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178641

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178642

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178643

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178644

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178645

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178646

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178647

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178648

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178649

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 7'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178650

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:10:57', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cef03ec9-0f7e-4635-bc4e-8badcf8ca6bb'	System	13 Oct 2020 00:11:19
User entered 'Yes (Y)'	System	13 Oct 2020 00:11:19

FDA-CBER-2022-1614-3178651

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:04', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cef03ec9-0f7e-4635-bc4e-8badcf8ca6bb'	System	13 Oct 2020 00:11:19
User entered '98.2'	System	13 Oct 2020 00:11:19

FDA-CBER-2022-1614-3178652

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:09', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cef03ec9-0f7e-4635-bc4e-8badcf8ca6bb'	System	13 Oct 2020 00:11:19
User entered 'No (N)'	System	13 Oct 2020 00:11:19

FDA-CBER-2022-1614-3178653

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:12', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cef03ec9-0f7e-4635-bc4e-8badcf8ca6bb'	System	13 Oct 2020 00:11:19
User entered '12 Oct 2020 19:11'	System	13 Oct 2020 00:11:19

FDA-CBER-2022-1614-3178654

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178655

US3752245
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178656

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:45', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd6cb12d9-0fe5-4978-bc8d-6f869ad910e5'	System	06 Oct 2020 18:52:16
User entered 'None (1)'	System	06 Oct 2020 18:52:16

FDA-CBER-2022-1614-3178658

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:49', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd6cb12d9-0fe5-4978-bc8d-6f869ad910e5'	System	06 Oct 2020 18:52:16
User entered 'No (N)'	System	06 Oct 2020 18:52:16

FDA-CBER-2022-1614-3178659

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:54', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd6cb12d9-0fe5-4978-bc8d-6f869ad910e5'	System	06 Oct 2020 18:52:16
User entered 'No (N)'	System	06 Oct 2020 18:52:16

FDA-CBER-2022-1614-3178660

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:51:58', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd6cb12d9-0fe5-4978-bc8d-6f869ad910e5'	System	06 Oct 2020 18:52:16
User entered 'None (1)'	System	06 Oct 2020 18:52:16

FDA-CBER-2022-1614-3178661

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd6cb12d9-0fe5-4978-bc8d-6f869ad910e5'	System	06 Oct 2020 18:52:16
User entered '06 Oct 2020 13:52'	System	06 Oct 2020 18:52:16

FDA-CBER-2022-1614-3178662

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 13:50'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178663

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 16:20'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178664

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:49', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'bea2141f-d98f-41ef-abce-eee0c9810d0d'	System	06 Oct 2020 22:17:13
User entered 'None (1)'	System	06 Oct 2020 22:17:13

FDA-CBER-2022-1614-3178666

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:53', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'bea2141f-d98f-41ef-abce-eee0c9810d0d'	System	06 Oct 2020 22:17:13
User entered 'No (N)'	System	06 Oct 2020 22:17:13

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:16:58', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'bea2141f-d98f-41ef-abce-eee0c9810d0d'	System	06 Oct 2020 22:17:13
User entered 'No (N)'	System	06 Oct 2020 22:17:13

FDA-CBER-2022-1614-3178668

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'bea2141f-d98f-41ef-abce-eee0c9810d0d'	System	06 Oct 2020 22:17:13
User entered 'None (1)'	System	06 Oct 2020 22:17:13

FDA-CBER-2022-1614-3178669

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:05', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'bea2141f-d98f-41ef-abce-eee0c9810d0d'	System	06 Oct 2020 22:17:13
User entered '06 Oct 2020 17:17'	System	06 Oct 2020 22:17:13

FDA-CBER-2022-1614-3178670

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 17:15'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178671

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178672

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 2'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178673

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:01:56', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2c39524c-498a-433a-81f7-33f45862c588'	System	07 Oct 2020 18:02:55
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 18:02:55

FDA-CBER-2022-1614-3178674

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:02:29', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2c39524c-498a-433a-81f7-33f45862c588'	System	07 Oct 2020 18:02:55
User entered 'No (N)'	System	07 Oct 2020 18:02:55

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:02:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2c39524c-498a-433a-81f7-33f45862c588'	System	07 Oct 2020 18:02:55
User entered 'No (N)'	System	07 Oct 2020 18:02:55

FDA-CBER-2022-1614-3178676

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:02:47', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2c39524c-498a-433a-81f7-33f45862c588'	System	07 Oct 2020 18:02:55
User entered 'None (1)'	System	07 Oct 2020 18:02:55

FDA-CBER-2022-1614-3178677

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:02:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2c39524c-498a-433a-81f7-33f45862c588'	System	07 Oct 2020 18:02:55
User entered '07 Oct 2020 13:02'	System	07 Oct 2020 18:02:55

FDA-CBER-2022-1614-3178678

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178679

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178680

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 3'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178681

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:04:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '295e89e3-5326-4c3f-93ca-1c16d41ec2c2'	System	09 Oct 2020 10:05:23
User entered 'None (1)'	System	09 Oct 2020 10:05:23

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:04:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '295e89e3-5326-4c3f-93ca-1c16d41ec2c2'	System	09 Oct 2020 10:05:23
User entered 'No (N)'	System	09 Oct 2020 10:05:23

FDA-CBER-2022-1614-3178683

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '295e89e3-5326-4c3f-93ca-1c16d41ec2c2'	System	09 Oct 2020 10:05:23
User entered 'No (N)'	System	09 Oct 2020 10:05:23

FDA-CBER-2022-1614-3178684

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:17', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '295e89e3-5326-4c3f-93ca-1c16d41ec2c2'	System	09 Oct 2020 10:05:23
User entered 'None (1)'	System	09 Oct 2020 10:05:23

FDA-CBER-2022-1614-3178685

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '295e89e3-5326-4c3f-93ca-1c16d41ec2c2'	System	09 Oct 2020 10:05:23
User entered '09 Oct 2020 05:05'	System	09 Oct 2020 10:05:23

FDA-CBER-2022-1614-3178686

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178687

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178688

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 4'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178689

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:00:57', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '28bc8d13-5cef-461c-ba24-2be84b9dd164'	System	09 Oct 2020 17:01:22
User entered 'None (1)'	System	09 Oct 2020 17:01:22

FDA-CBER-2022-1614-3178690

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:01', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '28bc8d13-5cef-461c-ba24-2be84b9dd164'	System	09 Oct 2020 17:01:22
User entered 'No (N)'	System	09 Oct 2020 17:01:22

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:05', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '28bc8d13-5cef-461c-ba24-2be84b9dd164'	System	09 Oct 2020 17:01:22
User entered 'No (N)'	System	09 Oct 2020 17:01:22

FDA-CBER-2022-1614-3178692

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:07', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '28bc8d13-5cef-461c-ba24-2be84b9dd164'	System	09 Oct 2020 17:01:22
User entered 'None (1)'	System	09 Oct 2020 17:01:22

FDA-CBER-2022-1614-3178693

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '28bc8d13-5cef-461c-ba24-2be84b9dd164'	System	09 Oct 2020 17:01:22
User entered '09 Oct 2020 12:01'	System	09 Oct 2020 17:01:22

FDA-CBER-2022-1614-3178694

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178695

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178696

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 5'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178698

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178699

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178700

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178701

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178702

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178704

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178705

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178706

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 6'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178708

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178709

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178710

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178711

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178712

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178714

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178715

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178716

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 7'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178717

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:20', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a634ad4d-21a4-4a85-83fb-3c6f8b146ade'	System	13 Oct 2020 00:11:43
User entered 'None (1)'	System	13 Oct 2020 00:11:43

FDA-CBER-2022-1614-3178718

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:24', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a634ad4d-21a4-4a85-83fb-3c6f8b146ade'	System	13 Oct 2020 00:11:43
User entered 'No (N)'	System	13 Oct 2020 00:11:43

FDA-CBER-2022-1614-3178719

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:30', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a634ad4d-21a4-4a85-83fb-3c6f8b146ade'	System	13 Oct 2020 00:11:43
User entered 'No (N)'	System	13 Oct 2020 00:11:43

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a634ad4d-21a4-4a85-83fb-3c6f8b146ade'	System	13 Oct 2020 00:11:43
User entered 'None (1)'	System	13 Oct 2020 00:11:43

FDA-CBER-2022-1614-3178721

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:36', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a634ad4d-21a4-4a85-83fb-3c6f8b146ade'	System	13 Oct 2020 00:11:43
User entered '12 Oct 2020 19:11'	System	13 Oct 2020 00:11:43

FDA-CBER-2022-1614-3178722

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178723

US3752245
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178724

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178725

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:06', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'None (0)'	System	06 Oct 2020 18:52:39

FDA-CBER-2022-1614-3178726

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'None (0)'	System	06 Oct 2020 18:52:39

FDA-CBER-2022-1614-3178727

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'None (0)'	System	06 Oct 2020 18:52:39

FDA-CBER-2022-1614-3178728

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:26', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'None (0)'	System	06 Oct 2020 18:52:39

FDA-CBER-2022-1614-3178729

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:28', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'None (0)'	System	06 Oct 2020 18:52:39

FDA-CBER-2022-1614-3178730

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:31', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'None (0)'	System	06 Oct 2020 18:52:39

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:34', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered 'No (N)'	System	06 Oct 2020 18:52:39

FDA-CBER-2022-1614-3178732

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T13:52:38', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'cbfa26fe-0772-46dd-84ed-5862f0dcd715'	System	06 Oct 2020 18:52:39
User entered '06 Oct 2020 13:52'	System	06 Oct 2020 18:52:39

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 13:50'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178734

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 16:20'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178735

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'None (0)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178737

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:13', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'None (0)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178738

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:16', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'None (0)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178739

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:19', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'None (0)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178740

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:22', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'None (0)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178741

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'None (0)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178742

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:27', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered 'No (N)'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178743

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-06T17:17:31', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '139175a1-5b51-47d5-8231-b18f0c9d5f8f'	System	06 Oct 2020 22:17:36
User entered '06 Oct 2020 17:17'	System	06 Oct 2020 22:17:36

FDA-CBER-2022-1614-3178744

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '06 Oct 2020 17:15'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178745

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178746

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 2'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:02:55', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'None (0)'	System	07 Oct 2020 18:03:24

FDA-CBER-2022-1614-3178748

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'None (0)'	System	07 Oct 2020 18:03:24

FDA-CBER-2022-1614-3178749

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'None (0)'	System	07 Oct 2020 18:03:24

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:06', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'None (0)'	System	07 Oct 2020 18:03:24

FDA-CBER-2022-1614-3178751

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'None (0)'	System	07 Oct 2020 18:03:24

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:13', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'None (0)'	System	07 Oct 2020 18:03:24

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:18', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered 'No (N)'	System	07 Oct 2020 18:03:24

FDA-CBER-2022-1614-3178754

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-07T13:03:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'a39751f8-9259-496e-9d28-7613474ea80f'	System	07 Oct 2020 18:03:24
User entered '07 Oct 2020 13:03'	System	07 Oct 2020 18:03:24

FDA-CBER-2022-1614-3178755

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178756

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178757

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 3'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:30', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'None (0)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178759

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:35', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'None (0)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178760

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'None (0)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178761

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:43', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'None (0)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178762

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'None (0)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178763

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:05:49', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'None (0)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178764

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:06:01', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered 'No (N)'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178765

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T05:06:08', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '35e7ab61-21cc-4e06-b972-6a876bce8853'	System	09 Oct 2020 10:06:13
User entered '09 Oct 2020 05:06'	System	09 Oct 2020 10:06:13

FDA-CBER-2022-1614-3178766

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178767

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178768

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 4'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178769

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:15', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'None (0)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178770

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:20', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'None (0)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178771

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:22', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'None (0)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178772

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:28', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'None (0)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178773

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:33', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'None (0)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178774

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:36', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'None (0)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178775

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered 'No (N)'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178776

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-09T12:01:42', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b15f12b0-ee00-49f0-8e28-a9692c61fe13'	System	09 Oct 2020 17:01:50
User entered '09 Oct 2020 12:01'	System	09 Oct 2020 17:01:50

FDA-CBER-2022-1614-3178777

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178778

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178779

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 5'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178781

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178782

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178783

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178785

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178786

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178787

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178788

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178790

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 6'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178792

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178793

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178794

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178795

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178796

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178797

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48

FDA-CBER-2022-1614-3178799

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178801

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 7'	System	06 Oct 2020 18:36:45

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:42', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'None (0)'	System	13 Oct 2020 00:12:09

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:45', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'None (0)'	System	13 Oct 2020 00:12:09

FDA-CBER-2022-1614-3178804

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:48', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'None (0)'	System	13 Oct 2020 00:12:09

FDA-CBER-2022-1614-3178805

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:50', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'None (0)'	System	13 Oct 2020 00:12:09

FDA-CBER-2022-1614-3178806

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:53', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'None (0)'	System	13 Oct 2020 00:12:09

FDA-CBER-2022-1614-3178807

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:11:58', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'None (0)'	System	13 Oct 2020 00:12:09

FDA-CBER-2022-1614-3178808

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:12:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered 'No (N)'	System	13 Oct 2020 00:12:09

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-10-12T19:12:04', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '243876f7-4e54-41ce-9cf8-2663919ce33d'	System	13 Oct 2020 00:12:09
User entered '12 Oct 2020 19:12'	System	13 Oct 2020 00:12:09

FDA-CBER-2022-1614-3178810

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178811

US3752245
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:46:43
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

FDA-CBER-2022-1614-3178812

US3752245
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:43:26

US3752245
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:43:26

US3752245
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 12:43:26

US3752245
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 12:43:26

FDA-CBER-2022-1614-3178816

US3752245
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:05:00

US3752245
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	21 Oct 2020 14:05:00

FDA-CBER-2022-1614-3178818

US3752245
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:05:16

FDA-CBER-2022-1614-3178819

US3752245
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:05:16

FDA-CBER-2022-1614-3178820

US3752245
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Oct 2020 14:05:16

US3752245
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:05:16

US3752245
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:05:21

US3752245
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	21 Oct 2020 14:05:21

FDA-CBER-2022-1614-3178824

US3752245
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:04:24

FDA-CBER-2022-1614-3178825

US3752245
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:04:24

US3752245
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 15:04:24

US3752245
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:04:24

FDA-CBER-2022-1614-3178828

US3752245
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:04:29

US3752245
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	27 Oct 2020 15:04:29

US3752245
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:08:54

FDA-CBER-2022-1614-3178831

US3752245
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '03 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:08:54

FDA-CBER-2022-1614-3178832

US3752245
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 15:08:54

US3752245
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'VISIT3'	System	05 Nov 2020 15:08:54

FDA-CBER-2022-1614-3178834

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '03 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178836

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '10:45'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178837

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '03 Nov 2020 10:45'	System	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178838

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '97.6' F	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178840

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178841

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '71'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178842

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'bpm'	System	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178843

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '18'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'breaths/min'	System	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178845

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '120'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178847

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '76'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178848

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered 'mmHg'	System	05 Nov 2020 15:09:23

FDA-CBER-2022-1614-3178849

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50

FDA-CBER-2022-1614-3178850

US3752245
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50

FDA-CBER-2022-1614-3178851

US3752245
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:09:33

US3752245
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '03 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:09:33

US3752245
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:09:50

US3752245
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '03 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:09:50

US3752245
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '10:47'	(b) (4), (b) (6)	05 Nov 2020 15:09:50

US3752245
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '03 Nov 2020 10:47'	System	05 Nov 2020 15:09:50

FDA-CBER-2022-1614-3178857

US3752245
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:09:54

US3752245
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	05 Nov 2020 15:09:54

FDA-CBER-2022-1614-3178859

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 64'	System	25 Aug 2020 19:59:00

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

FDA-CBER-2022-1614-3178865

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

FDA-CBER-2022-1614-3178870

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 19:59:00

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 19:59:00

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US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 71'	System	25 Aug 2020 19:59:00

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

FDA-CBER-2022-1614-3178891

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 19:59:00

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:33:26
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 19:59:00

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 78'	System	25 Aug 2020 19:59:00

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-08T13:23:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeeae4d01fe3'	System	08 Nov 2020 19:24:27
User entered 'Yes (Y)'	System	08 Nov 2020 19:24:27

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-08T13:23:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeeae4d01fe3'	System	08 Nov 2020 19:24:27
User entered 'No (N)'	System	08 Nov 2020 19:24:27

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-08T13:23:55', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeeae4d01fe3'	System	08 Nov 2020 19:24:27
User entered 'No (N)'	System	08 Nov 2020 19:24:27

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-08T13:24:05', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeeae4d01fe3'	System	08 Nov 2020 19:24:27
User entered 'Yes (Y)'	System	08 Nov 2020 19:24:27

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-08T13:24:12', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeeae4d01fe3'	System	08 Nov 2020 19:24:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 19:24:27

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-08T13:24:17', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeeae4d01fe3'	System	08 Nov 2020 19:24:27
User entered '08 Nov 2020 13:24:17'	System	08 Nov 2020 19:24:27

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 19:59:00

US3752245
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:54:48
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 19:59:00

FDA-CBER-2022-1614-3178924

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-22T08:55:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fbd694e6-0a39-402e-9dd7-d211bee5991c'	System	22 Nov 2020 14:56:01
User entered 'Yes (Y)'	System	22 Nov 2020 14:56:01

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-22T08:55:07', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fbd694e6-0a39-402e-9dd7-d211bee5991c'	System	22 Nov 2020 14:56:01
User entered 'No (N)'	System	22 Nov 2020 14:56:01

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-22T08:55:13', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fbd694e6-0a39-402e-9dd7-d211bee5991c'	System	22 Nov 2020 14:56:01
User entered 'No (N)'	System	22 Nov 2020 14:56:01

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-22T08:55:24', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fbd694e6-0a39-402e-9dd7-d211bee5991c'	System	22 Nov 2020 14:56:01
User entered 'Yes (Y)'	System	22 Nov 2020 14:56:01

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-22T08:55:40', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fbd694e6-0a39-402e-9dd7-d211bee5991c'	System	22 Nov 2020 14:56:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 14:56:01

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-22T08:55:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fbd694e6-0a39-402e-9dd7-d211bee5991c'	System	22 Nov 2020 14:56:01
User entered '22 Nov 2020 08:55:52'	System	22 Nov 2020 14:56:01

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-26T04:10:45', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd90c0fa2-6826-4384-b325-7bacd3639979'	System	26 Nov 2020 10:11:05
User entered 'No (N)'	System	26 Nov 2020 10:11:05

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-26T04:10:58', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd90c0fa2-6826-4384-b325-7bacd3639979'	System	26 Nov 2020 10:11:05
User entered 'No (N)'	System	26 Nov 2020 10:11:05

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-11-26T04:11:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd90c0fa2-6826-4384-b325-7bacd3639979'	System	26 Nov 2020 10:11:05
User entered '26 Nov 2020 04:11:03'	System	26 Nov 2020 10:11:05

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-03T05:11:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fede8bb7-5bbb-4bf8-8b85-8dbb76844891'	System	03 Dec 2020 11:12:07
User entered 'No (N)'	System	03 Dec 2020 11:12:07

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-03T05:11:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fede8bb7-5bbb-4bf8-8b85-8dbb76844891'	System	03 Dec 2020 11:12:07
User entered 'No (N)'	System	03 Dec 2020 11:12:07

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-03T05:12:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'fede8bb7-5bbb-4bf8-8b85-8dbb76844891'	System	03 Dec 2020 11:12:07
User entered '03 Dec 2020 05:12:03'	System	03 Dec 2020 11:12:07

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-21T14:01:44', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd4dafdf8-3bf7-4c56-b2e5-f3df8a68f334'	System	21 Dec 2020 21:02:08
User entered 'No (N)'	System	21 Dec 2020 21:02:08

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-21T14:01:55', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd4dafdf8-3bf7-4c56-b2e5-f3df8a68f334'	System	21 Dec 2020 21:02:08
User entered 'No (N)'	System	21 Dec 2020 21:02:08

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-21T14:02:05', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'd4dafdf8-3bf7-4c56-b2e5-f3df8a68f334'	System	21 Dec 2020 21:02:08
User entered '21 Dec 2020 14:02:05'	System	21 Dec 2020 21:02:08

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-28T15:13:19', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b10c9f2c-8497-4fa3-a782-8c4f5520bb16'	System	29 Dec 2020 01:20:01
User entered 'No (N)'	System	29 Dec 2020 01:20:01

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-28T15:13:24', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b10c9f2c-8497-4fa3-a782-8c4f5520bb16'	System	29 Dec 2020 01:20:01
User entered 'No (N)'	System	29 Dec 2020 01:20:01

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2020-12-28T15:13:28', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'b10c9f2c-8497-4fa3-a782-8c4f5520bb16'	System	29 Dec 2020 01:20:01
User entered '28 Dec 2020 15:13:28'	System	29 Dec 2020 01:20:01

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-04T11:13:43', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '5774df25-f878-4c7b-af09-7ddba76ea742'	System	04 Jan 2021 17:13:53
User entered 'No (N)'	System	04 Jan 2021 17:13:53

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-04T11:13:47', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '5774df25-f878-4c7b-af09-7ddba76ea742'	System	04 Jan 2021 17:13:53
User entered 'No (N)'	System	04 Jan 2021 17:13:53

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-04T11:13:52', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '5774df25-f878-4c7b-af09-7ddba76ea742'	System	04 Jan 2021 17:13:53
User entered '04 Jan 2021 11:13:52'	System	04 Jan 2021 17:13:53

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-07T11:58:05', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '6a7ec45b-b367-4343-9c9e-4305517bdde2'	System	07 Jan 2021 17:58:21
User entered 'No (N)'	System	07 Jan 2021 17:58:21

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-07T11:58:13', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '6a7ec45b-b367-4343-9c9e-4305517bdde2'	System	07 Jan 2021 17:58:21
User entered 'No (N)'	System	07 Jan 2021 17:58:21

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-07T11:58:18', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '6a7ec45b-b367-4343-9c9e-4305517bdde2'	System	07 Jan 2021 17:58:21
User entered '07 Jan 2021 11:58:18'	System	07 Jan 2021 17:58:21

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-14T09:40:26', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '89a57306-df11-40bf-b2a9-783020726ec3'	System	14 Jan 2021 15:40:38
User entered 'No (N)'	System	14 Jan 2021 15:40:38

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-14T09:40:29', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '89a57306-df11-40bf-b2a9-783020726ec3'	System	14 Jan 2021 15:40:38
User entered 'No (N)'	System	14 Jan 2021 15:40:38

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-14T09:40:34', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '89a57306-df11-40bf-b2a9-783020726ec3'	System	14 Jan 2021 15:40:38
User entered '14 Jan 2021 09:40:34'	System	14 Jan 2021 15:40:38

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-21T09:34:07', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e95a09fd-4d3c-4ea4-8710-5524222eca75'	System	21 Jan 2021 15:34:17
User entered 'No (N)'	System	21 Jan 2021 15:34:17

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-21T09:34:10', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e95a09fd-4d3c-4ea4-8710-5524222eca75'	System	21 Jan 2021 15:34:17
User entered 'No (N)'	System	21 Jan 2021 15:34:17

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-01-21T09:34:14', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e95a09fd-4d3c-4ea4-8710-5524222eca75'	System	21 Jan 2021 15:34:17
User entered '21 Jan 2021 09:34:14'	System	21 Jan 2021 15:34:17

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-01T15:07:02', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecd66b03-8630-45a9-9cf1-a0c551b35801'	System	01 Feb 2021 21:07:35
User entered 'No (N)'	System	01 Feb 2021 21:07:35

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-01T15:07:09', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecd66b03-8630-45a9-9cf1-a0c551b35801'	System	01 Feb 2021 21:07:35
User entered 'Yes (Y)'	System	01 Feb 2021 21:07:35

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-01T15:07:21', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecd66b03-8630-45a9-9cf1-a0c551b35801'	System	01 Feb 2021 21:07:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 21:07:35

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-01T15:07:25', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecd66b03-8630-45a9-9cf1-a0c551b35801'	System	01 Feb 2021 21:07:35
User entered '01 Feb 2021 15:07:25'	System	01 Feb 2021 21:07:35

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-04T10:31:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e211f7e1-a352-484d-a540-c22b2feaba3b'	System	04 Feb 2021 16:32:06
User entered 'No (N)'	System	04 Feb 2021 16:32:06

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-04T10:31:59', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e211f7e1-a352-484d-a540-c22b2feaba3b'	System	04 Feb 2021 16:32:06
User entered 'No (N)'	System	04 Feb 2021 16:32:06

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-04T10:32:03', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'e211f7e1-a352-484d-a540-c22b2feaba3b'	System	04 Feb 2021 16:32:06
User entered '04 Feb 2021 10:32:03'	System	04 Feb 2021 16:32:06

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-11T02:21:39', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c3355665-bc0e-48b9-860f-620c15a882c8'	System	11 Feb 2021 08:21:50
User entered 'No (N)'	System	11 Feb 2021 08:21:50

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-11T02:21:42', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c3355665-bc0e-48b9-860f-620c15a882c8'	System	11 Feb 2021 08:21:50
User entered 'No (N)'	System	11 Feb 2021 08:21:50

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-11T02:21:45', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'c3355665-bc0e-48b9-860f-620c15a882c8'	System	11 Feb 2021 08:21:50
User entered '11 Feb 2021 02:21:45'	System	11 Feb 2021 08:21:50

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-22T22:50:38', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '377e9b77-b555-4858-b469-3aaec7bcd425'	System	23 Feb 2021 04:51:10
User entered 'No (N)'	System	23 Feb 2021 04:51:10

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-22T22:50:40', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '377e9b77-b555-4858-b469-3aaec7bcd425'	System	23 Feb 2021 04:51:10
User entered 'No (N)'	System	23 Feb 2021 04:51:10

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-22T22:50:44', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '377e9b77-b555-4858-b469-3aaec7bcd425'	System	23 Feb 2021 04:51:10
User entered '22 Feb 2021 22:50:44'	System	23 Feb 2021 04:51:10

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-25T05:08:55-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '56f62e4e-3c7d-4881-97d3-8756a90bfa3c'	System	25 Feb 2021 11:09:12
User entered 'No (N)'	System	25 Feb 2021 11:09:12

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-25T05:09:06-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '56f62e4e-3c7d-4881-97d3-8756a90bfa3c'	System	25 Feb 2021 11:09:12
User entered 'No (N)'	System	25 Feb 2021 11:09:12

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-02-25T05:09:10-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '56f62e4e-3c7d-4881-97d3-8756a90bfa3c'	System	25 Feb 2021 11:09:12
User entered '25 Feb 2021 05:09:10'	System	25 Feb 2021 11:09:12

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-04T11:31:46-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecf897b1-6534-408a-89aa-6df96b6e0b34'	System	04 Mar 2021 17:32:00
User entered 'No (N)'	System	04 Mar 2021 17:32:00

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-04T11:31:49-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecf897b1-6534-408a-89aa-6df96b6e0b34'	System	04 Mar 2021 17:32:00
User entered 'No (N)'	System	04 Mar 2021 17:32:00

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-04T11:31:52-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'ecf897b1-6534-408a-89aa-6df96b6e0b34'	System	04 Mar 2021 17:32:00
User entered '04 Mar 2021 11:31:52'	System	04 Mar 2021 17:32:00

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-18T07:18:41-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'dce79ac8-d227-4868-b7ac-90dcdf6a2ba5'	System	18 Mar 2021 12:18:51
User entered 'No (N)'	System	18 Mar 2021 12:18:51

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-18T07:18:45-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'dce79ac8-d227-4868-b7ac-90dcdf6a2ba5'	System	18 Mar 2021 12:18:51
User entered 'No (N)'	System	18 Mar 2021 12:18:51

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-18T07:18:49-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'dce79ac8-d227-4868-b7ac-90dcdf6a2ba5'	System	18 Mar 2021 12:18:51
User entered '18 Mar 2021 07:18:49'	System	18 Mar 2021 12:18:51

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-02T07:29:48-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'dc651c7a-cd2f-4ed5-8244-36becfc6a0bf'	System	02 Apr 2021 12:30:02
User entered 'No (N)'	System	02 Apr 2021 12:30:02

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-02T07:29:54-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'dc651c7a-cd2f-4ed5-8244-36becfc6a0bf'	System	02 Apr 2021 12:30:02
User entered 'No (N)'	System	02 Apr 2021 12:30:02

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-02T07:29:57-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: 'dc651c7a-cd2f-4ed5-8244-36becfc6a0bf'	System	02 Apr 2021 12:30:02
User entered '02 Apr 2021 07:29:57'	System	02 Apr 2021 12:30:02

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-08T08:29:14-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '0f716966-a7e7-4400-98fa-3bfb0f34ba70'	System	08 Apr 2021 13:29:24
User entered 'No (N)'	System	08 Apr 2021 13:29:24

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-08T08:29:18-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '0f716966-a7e7-4400-98fa-3bfb0f34ba70'	System	08 Apr 2021 13:29:24
User entered 'No (N)'	System	08 Apr 2021 13:29:24

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-08T08:29:22-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '0f716966-a7e7-4400-98fa-3bfb0f34ba70'	System	08 Apr 2021 13:29:24
User entered '08 Apr 2021 08:29:22'	System	08 Apr 2021 13:29:24

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-19T23:07:34-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '094dfb50-bddf-474e-8c4f-9c0b2b93aa49'	System	20 Apr 2021 04:07:55
User entered 'No (N)'	System	20 Apr 2021 04:07:55

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-19T23:07:47-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '094dfb50-bddf-474e-8c4f-9c0b2b93aa49'	System	20 Apr 2021 04:07:55
User entered 'No (N)'	System	20 Apr 2021 04:07:55

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-19T23:07:52-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '094dfb50-bddf-474e-8c4f-9c0b2b93aa49'	System	20 Apr 2021 04:07:55
User entered '19 Apr 2021 23:07:52'	System	20 Apr 2021 04:07:55

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-26T10:25:01-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90a83715-cef7-476f-9088-ab3060246156'	System	26 Apr 2021 15:25:11
User entered 'No (N)'	System	26 Apr 2021 15:25:11

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-26T10:25:03-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90a83715-cef7-476f-9088-ab3060246156'	System	26 Apr 2021 15:25:11
User entered 'No (N)'	System	26 Apr 2021 15:25:11

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-26T10:25:07-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '90a83715-cef7-476f-9088-ab3060246156'	System	26 Apr 2021 15:25:11
User entered '26 Apr 2021 10:25:07'	System	26 Apr 2021 15:25:11

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-29T04:36:46-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '11beda3f-9111-4e5a-9027-d34986409009'	System	29 Apr 2021 09:37:05
User entered 'No (N)'	System	29 Apr 2021 09:37:05

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-29T04:36:49-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '11beda3f-9111-4e5a-9027-d34986409009'	System	29 Apr 2021 09:37:05
User entered 'No (N)'	System	29 Apr 2021 09:37:05

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-04-29T04:36:53-05:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '11beda3f-9111-4e5a-9027-d34986409009'	System	29 Apr 2021 09:37:05
User entered '29 Apr 2021 04:36:53'	System	29 Apr 2021 09:37:05

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:33:26

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US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:33:26

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US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:33:26

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:33:26

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:33:26

US3752245
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:46:43
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:33:26

US3752245

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:46:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-04T11:31:58-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '491896b0-89ab-45f9-9738-44ede22fae6b'	System	04 Mar 2021 17:32:12
User entered 'No (N)'	System	04 Mar 2021 17:32:12

US3752245
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 09:46:43
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:50:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1627f959aa85a3a0)', Time: '2021-03-04T11:32:05-06:00', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '491896b0-89ab-45f9-9738-44ede22fae6b'	System	04 Mar 2021 17:32:12
User entered '04 Mar 2021 11:32:05'	System	04 Mar 2021 17:32:12

US3752245
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:07:56

US3752245
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:07:56

US3752245
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Nov 2020 15:07:56

US3752245
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 15:07:56

US3752245
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 15:08:01

US3752245
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:14:50
User entered '1'	System	30 Nov 2020 15:08:01

US3752245
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:38:40

US3752245
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '04 Jan 2021'	(b) (4), (b) (6)	04 Jan 2021 20:38:40

US3752245
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Jan 2021 20:38:40

US3752245
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:38:40

FDA-CBER-2022-1614-3179309

US3752245
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:38:48

US3752245
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered '1'	System	04 Jan 2021 20:38:48

US3752245
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Feb 2021 19:07:23

US3752245
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered '2 Feb 2021'	Amanda Horn (b) (4) (b) (4)	10 Feb 2021 19:07:23

US3752245
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	10 Feb 2021 19:07:23

US3752245
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:05:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Feb 2021 19:07:23

US3752245
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Feb 2021 19:07:28

US3752245
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered '1'	System	10 Feb 2021 19:07:28

FDA-CBER-2022-1614-3179317

US3752245
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	14 Mar 2021 18:09:08
User entered 'Yes (Y)'	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 19:25:37

US3752245
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	14 Mar 2021 18:09:08
User entered '02 Mar 2021'	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 19:25:37

FDA-CBER-2022-1614-3179319

US3752245
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	14 Mar 2021 18:09:08
User entered 'Contact Made (CONTACT MADE)'	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 19:25:37

US3752245
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:46:43
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	14 Mar 2021 18:09:08
User entered empty.	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 19:25:37

FDA-CBER-2022-1614-3179321

US3752245
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	14 Mar 2021 18:09:08
User entered 'Yes (Y)'	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 19:25:43

US3752245
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered '1'	System	12 Mar 2021 19:25:43

US3752245
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:11

FDA-CBER-2022-1614-3179324

US3752245
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '29 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:11

US3752245
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Clinic (Clinic)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:11

FDA-CBER-2022-1614-3179326

US3752245
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered 'VISIT4'	System	29 Mar 2021 18:25:11

FDA-CBER-2022-1614-3179327

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '29 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

FDA-CBER-2022-1614-3179329

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '11:30'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered '29 Mar 2021 11:30'	System	29 Mar 2021 18:25:47

FDA-CBER-2022-1614-3179331

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '98.0' F	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Oral (Oral)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '74'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered 'bpm'	System	29 Mar 2021 18:25:47

FDA-CBER-2022-1614-3179336

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '16'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered 'breaths/min'	System	29 Mar 2021 18:25:47

FDA-CBER-2022-1614-3179338

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '130'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered 'mmHg'	System	29 Mar 2021 18:25:47

FDA-CBER-2022-1614-3179340

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '76'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:47

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered 'mmHg'	System	29 Mar 2021 18:25:47

FDA-CBER-2022-1614-3179342

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37

FDA-CBER-2022-1614-3179343

US3752245
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37

FDA-CBER-2022-1614-3179344

US3752245
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:58

US3752245
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '29 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:25:58

FDA-CBER-2022-1614-3179346

US3752245
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:26:16

US3752245
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '29 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:26:16

US3752245
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '11:41'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:26:16

US3752245
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered '29 Mar 2021 11:41'	System	29 Mar 2021 18:26:16

US3752245
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:26:21

US3752245
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:46:43
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:28:37
User entered '1'	System	29 Mar 2021 18:26:21

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:46:43
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:40
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:48
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 11-DEC-2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:12:17
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 11-DEC-2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Data has been entered' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 17:34:57
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 11-DEC-2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 13:02:33
User entered '10 Dec 2020'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:21

FDA-CBER-2022-1614-3179353

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:46:43
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:40
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:48
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '13:30'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:21

FDA-CBER-2022-1614-3179354

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:46:43
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:40
User entered '10 Dec 2020 13:30'	System	11 Dec 2020 21:43:21

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:46:43
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:40
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:48
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Safety Call (Safety Call)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:21

FDA-CBER-2022-1614-3179356

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:46:43
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:40
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:48
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:21

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 1 (Day 1)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:12:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 16:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 16:51:01
User entered '7 Dec 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 16:50:48
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179361

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28
User entered empty.	System	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179362

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '99.4' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179363

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179364

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179366

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179368

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179369

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179370

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179371

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179372

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179373

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179374

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179375

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179376

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179377

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179378

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:50:48

FDA-CBER-2022-1614-3179379

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 2 (Day 2)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179380

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:12:43
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '8 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179382

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179383

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28
User entered empty.	System	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179384

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179385

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179386

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179387

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179388

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179389

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179390

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179391

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179392

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179393

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179394

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179395

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179396

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179397

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179398

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179399

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179400

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:51:01

FDA-CBER-2022-1614-3179401

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '9 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179406

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:13:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179418

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:13:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179419

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:13:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179423

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 4 (Day 4)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179424

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '10 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179425

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179426

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179428

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered missing code ND - Not Done.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179429

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179440

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179445

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179446

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179447

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179448

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '99'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179450

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '98.0' F	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 6 (Day 6)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179468

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '12 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '98'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179472

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '97.6' F	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179473

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '13 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179491

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179492

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '97'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179494

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '98.2' F	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:42:09
User closed query 'please verify as none as per source' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:52:02
Query 'please verify as none as per source' answered with 'data updated' (Site from CRA).	Lauren Evans (b) (4)	10 Mar 2021 21:25:45
Signature has been broken.	Lauren Evans (b) (4)	10 Mar 2021 21:25:38
User entered 'None (None)' reason for change: Data Entry Error	Lauren Evans (b) (4)	10 Mar 2021 21:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:24
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User opened query 'please verify as none as per source' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:15:35
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 16:56:28

FDA-CBER-2022-1614-3179511

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 8 (Day 8)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '14 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

FDA-CBER-2022-1614-3179514

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '99'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	14 Dec 2020 22:02:05

FDA-CBER-2022-1614-3179516

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '98.6' F	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

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US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

FDA-CBER-2022-1614-3179531

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:02:05

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179534

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '15 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179535

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179536

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '99'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179538

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '97.0' F	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179539

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179542

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

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US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179546

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179547

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179549

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 10 (Day 10)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '16 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179558

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '99'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179560

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '97.0' F	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179561

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (10)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:23:08

FDA-CBER-2022-1614-3179577

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Day 11 (Day 11)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179578

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '17 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179579

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179580

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '99'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
User entered '%'	System	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179582

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '97.2' F	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179583

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179587

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179594

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179597

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

FDA-CBER-2022-1614-3179598

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Symptom Log (11)
Generated On: 10 Jun 2021 09:46:43
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:23

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
User closed query 'please complete Generate Next COVID19 Assessment tab' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:51:38
Query 'please complete Generate Next COVID19 Assessment tab' answered with 'completed' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 15:28:36
User opened query 'please complete Generate Next COVID19 Assessment tab' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:18:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

FDA-CBER-2022-1614-3179604

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

FDA-CBER-2022-1614-3179607

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:17:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:24:52

FDA-CBER-2022-1614-3179608

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:46:43
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:10:53
User entered '0'	System	18 Dec 2020 20:24:52

FDA-CBER-2022-1614-3179609

US3752245
Folder: Covid-19 Assessment 10 Dec 2020
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 09:46:43
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:11:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:21:35
User entered 'Yes (Y)'	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 15:28:16

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:20:45
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:20:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '13 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:21:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:21:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please provide the tracking details in query response for tracking purpose once its shipped.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 05:34:16
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please provide the tracking details in query response for tracking purpose once its shipped.' answered with '914897858529 914897884401' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	20 Jan 2021 15:03:25
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please provide the tracking details in query response for tracking purpose once its shipped.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:25:36
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:25:36
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' answered with 'It would've been shipped yesterday, but that was MLK day here and the shippers didn't run. So it's going out today' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 15:26:17
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:42:14

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:42:14
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F604825642' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:20:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 08:42:16
User entered '15 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:21:43
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please provide the tracking details in query response for tracking purpose once its shipped. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 05:34:59
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please provide the tracking details in query response for tracking purpose once its shipped. ' answered with '914897858529 914897884401' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	20 Jan 2021 15:03:41
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please provide the tracking details in query response for tracking purpose once its shipped. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:25:49
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:25:49
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' answered with 'It would've been shipped yesterday, but that was MLK day here and the shippers didn't run. So it's going out today' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 15:26:37
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:42:23

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:42:23
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F618985642' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:20:35
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 08:42:40
User entered '17 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

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US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

FDA-CBER-2022-1614-3179625

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

FDA-CBER-2022-1614-3179628

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:46:43
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

FDA-CBER-2022-1614-3179631

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:46:43
Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'NA (COVID-19 Negative) (NA)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

FDA-CBER-2022-1614-3179632

US3752245
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:22:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:25:33

US3752245
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:09:26
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:49

FDA-CBER-2022-1614-3179634

US3752245
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:09:26
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:49

FDA-CBER-2022-1614-3179635

US3752245
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:47
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:09:26
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Clinic (Clinic)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:43:49

US3752245
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:47
User entered 'SICKD1'	System	11 Dec 2020 21:43:49

FDA-CBER-2022-1614-3179637

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179638

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '10:05'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179640

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
User entered '11 Dec 2020 10:05'	System	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179641

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '63.0' in	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39
DataPoint set to visible.	System	11 Dec 2020 21:43:49

FDA-CBER-2022-1614-3179642

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '210.0' lb	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39
DataPoint set to visible.	System	11 Dec 2020 21:43:49

FDA-CBER-2022-1614-3179643

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '98.0' F	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179644

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Oral (Oral)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179645

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179646

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '87'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179647

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
User entered 'bpm'	System	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179648

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '16'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179649

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
User entered 'breaths/min'	System	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179650

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '132'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179651

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
User entered 'mmHg'	System	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179652

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:00
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '70'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179653

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43
User entered 'mmHg'	System	11 Dec 2020 21:44:39

FDA-CBER-2022-1614-3179654

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43

FDA-CBER-2022-1614-3179655

US3752245
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:46:43
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:43

FDA-CBER-2022-1614-3179656

US3752245
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:39
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:47

US3752245
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:46:43
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:50:39
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:47

FDA-CBER-2022-1614-3179658

US3752245
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:46:43
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:52

US3752245
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:46:43
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:10:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Dec 2020'	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:44:52

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:24

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:24

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:24

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:46:43
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 19:42:24

FDA-CBER-2022-1614-3179664

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179665

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:26:15
User entered '0'	Haylee Rowe (b) (4) (b) (4)	22 Apr 2021 14:57:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:42:54

FDA-CBER-2022-1614-3179666

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

US3752245

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:43

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:46:56
User signature succeeded.	Priyantha Wijewardane (b) (4)	22 Apr 2021 15:26:15
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated data ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	22 Apr 2021 14:57:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	Haylee Rowe (b) (4) (b) (4)	22 Apr 2021 14:57:16
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 06:43:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:42:54

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179669

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179670

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179671

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179672

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:36

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User entered empty.	System	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179674

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:46:43
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User entered empty.	System	20 Jan 2021 19:43:36

FDA-CBER-2022-1614-3179675

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:53

FDA-CBER-2022-1614-3179676

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:53

FDA-CBER-2022-1614-3179677

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '13:20'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:53

FDA-CBER-2022-1614-3179678

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:46:43
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User entered '20 Jan 2021 13:20'	System	20 Jan 2021 19:43:53

FDA-CBER-2022-1614-3179679

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:46:43
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:44:03

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:46:43
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:44:03

FDA-CBER-2022-1614-3179681

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:46:43
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '13:16'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:44:03

FDA-CBER-2022-1614-3179682

US3752245
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:46:43
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:48
User entered '20 Jan 2021 13:16'	System	20 Jan 2021 19:44:03

FDA-CBER-2022-1614-3179683

US3752245
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:46:43
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:27:21
User entered 'Yes (Y)' reason for change: New Information	Lauren Evans (b) (4)	06 Nov 2020 18:58:11
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:19:27

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
AEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:46:13
User entered 'USA-US113-2020-mRNA-1273-P301000009'	System	09 Nov 2020 14:46:07
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 14:46:07

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Adverse event

Audit	User	Time (GMT)
User closed query 'Per Safety: Any recent trauma to the face or the head? If yes, please add to AE form.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:35:20
User closed query 'Per Safety: Indicate if the subject had any infection of Herpes Simplex Virus infection, Lyme, Epstein Barr Virus, Cytomegalovirus, or other virus at the time of the event of Bell's palsy? If so, when was it diagnosed and add to AE form.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:35:19
Query 'Per Safety: Indicate if the subject had any infection of Herpes Simplex Virus infection, Lyme, Epstein Barr Virus, Cytomegalovirus, or other virus at the time of the event of Bell's palsy? If so, when was it diagnosed and add to AE form.' answered with 'nonone of these' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:02:49
Query 'Per Safety: Any recent trauma to the face or the head? If yes, please add to AE form.' answered with 'no' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:02:31
User opened query 'Per Safety: Any recent trauma to the face or the head? If yes, please add to AE form.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:58:35
User opened query 'Per Safety: Indicate if the subject had any infection of Herpes Simplex Virus infection, Lyme, Epstein Barr Virus, Cytomegalovirus, or other virus at the time of the event of Bell's palsy? If so, when was it diagnosed and add to AE form.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:58:10
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:38
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Facial cranial nerve disorders, PT: Facial paralysis, LLT: Bell's palsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 19:49:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 19:49:34
Data point term sent to Coder	System	08 Nov 2020 19:48:20
User entered 'BELL'S PALSY'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179686

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:27:40
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179687

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:27:44
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179688

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:27:46
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179689

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:27:51
User entered '6 Nov 2020'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179690

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:27:52
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	08 Nov 2020 19:48:26
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:26
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	08 Nov 2020 19:48:05
User entered '08:00'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Nov 2020 19:48:26
User entered '6 Nov 2020 08:00'	System	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:20:55
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:20:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:55
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179693

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:03:00
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'data changed' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:21:30
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:21:18
User entered '29 Dec 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:21:18
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 19:20:55
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:20:55
User entered '29 Dec 2021' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:20:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:00:51
Query 'Revised PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:00:32
User opened query 'Revised PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:00:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	13 Jan 2021 18:23:29
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	13 Jan 2021 18:23:29

FDA-CBER-2022-1614-3179694

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 18:26:00
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Dec 2020 21:12:36
Query 'PV Query: Please provide the event end date' answered with 'end time unknown' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 21:11:44
User opened query 'PV Query: Please provide the event end date' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:53:43
User closed query 'PV Query: Please provide the event end date' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:40:04
Query 'PV Query: Please provide the event end date' answered with 'ONGOING' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 20:20:36
User opened query 'PV Query: Please provide the event end date' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:02:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:59
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179695

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:28:01
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179696

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Severity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
User closed query 'PV Query: What was the grading system used to rate as grade 4? Was it HBS?' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:47:23
Query 'PV Query: What was the grading system used to rate as grade 4? Was it HBS?' answered with 'data udpated' (Site from Safety).	Jamie Pettus (b) (4)	25 Feb 2021 20:56:55
DataPoint Un-verified.	Jamie Pettus (b) (4)	25 Feb 2021 20:56:44
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	25 Feb 2021 20:56:44
User opened query 'PV Query: What was the grading system used to rate as grade 4? Was it HBS?' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:15:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:41:11
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:31:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amanda Horn (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:12
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:20
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179700

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:21
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:23
User entered '1'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:48
User entered '6 Nov 2020'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179703

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:50
User entered '7 Nov 2020'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:56
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:57
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:59
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179708

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:01
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:05
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:07
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:08
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
None

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:14
User entered '1'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

FDA-CBER-2022-1614-3179714

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:16
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
User closed query 'PV Query: Outcome has been updated to Recovering/Resolving hence please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:03:04
Query 'PV Query: Outcome has been updated to Recovering/Resolving hence please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data changed' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:21:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	03 Feb 2021 19:20:55
User opened query 'PV Query: Outcome has been updated to Recovering/Resolving hence please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:01:16
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:27:53
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not resolved as of yet' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:24:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:23:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 21:12:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 21:12:36

FDA-CBER-2022-1614-3179716

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:03:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:19
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	29 Apr 2021 22:28:36
User closed query 'per CDM RQ: response noted, please add unilateral to narrative' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:36:45
Query 'per CDM RQ: response noted, please add unilateral to narrative' answered with 'Added ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	22 Apr 2021 20:10:46
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL 06NOV2020 TO RULE OUT STROKE. CT WAS INCONCLUSIVE BUT ACCORDING TO THE SUBJECT THE MRI SHOWED NO EVIDENCE OF CURRENT, ACUTE STROKE BUT DID SHOW POSSIBLE STROKE IN THE PAST. SHE IS BEING TREATED FOR BELL'S PALSY AND WAS ALSO PRESCRIBED PLAVIX DUE TO POSSIBLE STROKE HISTORY. SHE FOLLOWS UP WITH HER PCP THIS WEEK TO DETERMINE LONG-TERM MANAGEMENT. HAD COMPLETE PARALYSIS. UNILATERAL FACIAL DROOP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	22 Apr 2021 20:10:18
User opened query 'per CDM RQ: response noted, please add unilateral to narrative' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:37:51
Query 'per CDM RQ: response noted, please add to narrative' canceled (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:37:39
User opened query 'per CDM RQ: response noted, please add to narrative' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:37:17
User closed query 'Per Safety: Was the event of Bell’s Palsy unilateral OR bilateral? Please add to narrative.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:37:17
User closed query 'Per Safety: Please report any pertinent results of neuroimaging-, laboratory-, or electrophysiological studies, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:36:58
User closed query 'Per Safety: Does the subject have any other medical finding that could indicate an alternative diagnosis of non-idiopathic peripheral facial paralysis?' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:36:56

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
User closed query 'Per Safety: Did the patient have any other symptoms at the time of onset or within 4 weeks of the onset? (Including but not limited to pain, rash/ vesicles, fever, symptoms of viral infections, otitis media, mastoiditis, cholesteatoma?)' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:36:54
User closed query 'Per Safety: Was the subject able to wrinkle the forehead OR to raise the eyebrows at the affected side?' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:36:53
User closed query 'Per Safety: Was it complete (paralysis) OR incomplete (paresis)? Please add to narrative.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:11:00
User closed query 'Per Safety: Did the subject have an acute-onset peripheral facial nerve palsy? ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:10:35
Query 'Per Safety: Does the subject have any other medical finding that could indicate an alternative diagnosis of non-idiopathic peripheral facial paralysis?' answered with 'no, none' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:05:39
Query 'Per Safety: Did the patient have any other symptoms at the time of onset or within 4 weeks of the onset? (Including but not limited to pain, rash/ vesicles, fever, symptoms of viral infections, otitis media, mastoiditis, cholesteatoma?)' answered with 'no' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:05:16
Query 'Per Safety: Was the subject able to wrinkle the forehead OR to raise the eyebrows at the affected side?' answered with 'yes' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:05:03
Query 'Per Safety: Was the event of Bell's Palsy unilateral OR bilateral? Please add to narrative.' answered with 'unilateral' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:04:44
Query 'Per Safety: Was it complete (paralysis) OR incomplete (paresis)? Please add to narrative.' answered with 'added' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:04:29
Query 'Per Safety: Please report any pertinent results of neuroimaging-, laboratory-, or electrophysiological studies, if applicable.' answered with 'none per the records' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:04:14
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:03:56
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:03:56

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL 06NOV2020 TO RULE OUT STROKE. CT WAS INCONCLUSIVE BUT ACCORDING TO THE SUBJECT THE MRI SHOWED NO EVIDENCE OF CURRENT, ACUTE STROKE BUT DID SHOW POSSIBLE STROKE IN THE PAST. SHE IS BEING TREATED FOR BELL'S PALSY AND WAS ALSO PRESCRIBED PLAVIX DUE TO POSSIBLE STROKE HISTORY. SHE FOLLOWS UP WITH HER PCP THIS WEEK TO DETERMINE LONG-TERM MANAGEMENT. Had complete paralysis' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:03:56
Query 'Per Safety: Did the subject have an acute-onset peripheral facial nerve palsy? ' answered with 'yes' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:03:03
User opened query 'Per Safety: Please report any pertinent results of neuroimaging-, laboratory-, or electrophysiological studies, if applicable.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:57:39
User opened query 'Per Safety: Does the subject have any other medical finding that could indicate an alternative diagnosis of non-idiopathic peripheral facial paralysis?' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:57:00
User opened query 'Per Safety: Did the patient have any other symptoms at the time of onset or within 4 weeks of the onset? (Including but not limited to pain, rash/ vesicles, fever, symptoms of viral infections, otitis media, mastoiditis, cholesteatoma?)' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:54:39
User opened query 'Per Safety: Was the subject able to wrinkle the forehead OR to raise the eyebrows at the affected side?' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:54:16
User opened query 'Per Safety: Was the event of Bell’s Palsy unilateral OR bilateral? Please add to narrative.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:53:56
User opened query 'Per Safety: Was it complete (paralysis) OR incomplete (paresis)? Please add to narrative.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:53:14
User opened query 'Per Safety: Did the subject have an acute-onset peripheral facial nerve palsy? ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:52:58

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User closed query 'PV Query: Please provide the type of influenza vaccine the subject received.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:28:22
User closed query 'PV Query: Please report if the patient has any history of Lyme disease. If yes, please provide details; if none, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:28:14
User closed query 'PV Query: Please provide the subject's medical history of cold sores, sore throat, genital warts, rash, or chronic fatigue. If no history, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:28:07
User closed query 'PV Query: Please provide any past or present serology tests conducted on the subject for viral infections (i.e. herpes simplex-zoster, EBV, Lyme). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:27:58
Query 'PV Query: Please provide the type of influenza vaccine the subject received.' answered with 'flue zone high dose quadravalant 0.7ml' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:31:12
Query 'PV Query: Please report if the patient has any history of Lyme disease. If yes, please provide details; if none, please state so.' answered with 'none' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:29:05
Query 'PV Query: Please provide the subject's medical history of cold sores, sore throat, genital warts, rash, or chronic fatigue. If no history, please state so.' answered with 'none' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:25:46
Query 'PV Query: Please provide any past or present serology tests conducted on the subject for viral infections (i.e. herpes simplex-zoster, EBV, Lyme). If none, please state so.' answered with 'we don't have records of any' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:25:34
User opened query 'PV Query: Please provide the type of influenza vaccine the subject received.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:56:14
User opened query 'PV Query: Please report if the patient has any history of Lyme disease. If yes, please provide details; if none, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:55:48

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the subject's medical history of cold sores, sore throat, genital warts, rash, or chronic fatigue. If no history, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:55:12
User opened query 'PV Query: Please provide any past or present serology tests conducted on the subject for viral infections (i.e. herpes simplex-zoster, EBV, Lyme). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:54:27
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:39:34
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:39:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:39:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RECORDS FAXED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:34:53
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'RECORDS FAXED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:34:46
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'FAXED' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	11 Dec 2020 21:34:18
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:03:17

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:03:08
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:02:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:32
User entered 'SUBJECT WAS ADMITTED TO HOSPITAL 06NOV2020 TO RULE OUT STROKE. CT WAS INCONCLUSIVE BUT ACCORDING TO THE SUBJECT THE MRI SHOWED NO EVIDENCE OF CURRENT, ACUTE STROKE BUT DID SHOW POSSIBLE STROKE IN THE PAST. SHE IS BEING TREATED FOR BELL'S PALSY AND WAS ALSO PRESCRIBED PLAVIX DUE TO POSSIBLE STROKE HISTORY. SHE FOLLOWS UP WITH HER PCP THIS WEEK TO DETERMINE LONG-TERM MANAGEMENT.'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Nov 2020 19:48:05

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:31:47
Data point term sent to Coder	System	18 Dec 2020 20:30:53
User entered 'NASAL CONGESTION'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '7 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User entered empty.	System	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '15 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User entered empty.	System	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

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US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '1'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

FDA-CBER-2022-1614-3179756

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User entered '0'	System	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05
User entered '1'	System	18 Dec 2020 20:30:04

US3752245
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:05

FDA-CBER-2022-1614-3179763

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09

FDA-CBER-2022-1614-3179764

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:31:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:31:48
Data point term sent to Coder	System	18 Dec 2020 20:30:53
User entered 'RUNNY NOSE'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '7 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User entered empty.	System	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '15 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User entered empty.	System	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

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US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

FDA-CBER-2022-1614-3179782

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

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US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '1'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User entered '0'	System	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09
User entered '1'	System	18 Dec 2020 20:30:35

US3752245
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:09

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US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13

FDA-CBER-2022-1614-3179800

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:32:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:32:49
Data point term sent to Coder	System	18 Dec 2020 20:31:53
User entered 'SORE THROAT'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '7 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User entered empty.	System	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '13 Dec 2020'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User entered empty.	System	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

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US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '1'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User entered '0'	System	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13
User entered '1'	System	18 Dec 2020 20:31:06

US3752245
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:46:43
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:16:13

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US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:46:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:25
User closed query 'Per Safety: Any recent procedures to the area (including cosmetic fillers or Botox)? If yes, please add to ConMed form.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:35:33
Query 'Per Safety: Any recent procedures to the area (including cosmetic fillers or Botox)? If yes, please add to ConMed form.' answered with 'no' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	31 Mar 2021 19:16:40
User opened query 'Per Safety: Any recent procedures to the area (including cosmetic fillers or Botox)? If yes, please add to ConMed form.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 18:59:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:19:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:31:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:00:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:00:55
Data point term sent to Coder	System	26 Aug 2020 18:21:01
User entered 'Metformin'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:31:34
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:31:36
User entered 'Type II diabetes mellitus'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:42:16
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:41:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:41:49
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:32:15
User entered '500' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:00:09
User entered '1000'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:26
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:28
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:42:02
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:32:15
User entered 'twice daily (BID)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:00:09
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:32
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:36
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:43
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:46
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:20:39

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:32:48
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:32:15
User entered '2'	System	10 Nov 2020 16:00:09
User entered '1'	System	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:20:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:02
Data point term sent to Coder	System	26 Aug 2020 18:22:04
User entered 'Fenofibrate'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:10
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

FDA-CBER-2022-1614-3179856

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:13
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:16
User entered '160'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:18
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:20
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:24
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

FDA-CBER-2022-1614-3179861

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:27
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:32
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:35
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:36
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

FDA-CBER-2022-1614-3179867

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:41
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:17

FDA-CBER-2022-1614-3179868

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:21:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:00
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 18:01:00
Data point term sent to Coder	System	26 Aug 2020 18:22:06
User entered 'Rosuvastatin'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

FDA-CBER-2022-1614-3179873

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:57
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

FDA-CBER-2022-1614-3179874

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:59
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:04
User entered '5'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:06
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:08
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:11
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:12
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:20
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:26
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:30
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:21:57

FDA-CBER-2022-1614-3179886

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:39
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:21:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:02
Data point term sent to Coder	System	26 Aug 2020 18:23:08
User entered 'Lexapro'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:34:58
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:01
User entered 'Depression'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:09
User entered '10'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:14
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:16
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:20
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:24
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:22:39

FDA-CBER-2022-1614-3179898

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:32
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:36
User entered 'un UNK 2010'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:39
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:50
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:35:55
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:22:39

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:07
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 18:01:07
Data point term sent to Coder	System	26 Aug 2020 18:24:10
User entered 'Azelastine'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:10
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:13
User entered 'Seasonal allergies'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:16
User entered '137'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:24
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 10:43:55
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:13:46
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:13:39
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:38:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:13:39
User entered 'mcg'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:39
User entered 'as needed (PRN)'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:40
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:46
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:48
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:52
User entered 'un UNK 2020'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:56
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:03
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:08
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:23:45

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:23
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 HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:13:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:13:39
Data point term sent to Coder	System	05 Sep 2020 15:12:14
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	05 Sep 2020 15:12:14
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 HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:11:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:11:40
Data point term sent to Coder	System	01 Sep 2020 14:23:27
Coding entries removed.	(b) (4), (b) (6)	01 Sep 2020 14:23:15
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 HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:17

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
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 18:01:17
Data point term sent to Coder	System	26 Aug 2020 18:27:17
User entered 'Albuterol HFA'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:26
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:29
User closed query 'Per CDM: This appears to be the Dose and not the Indication. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:48:40
Query 'Per CDM: This appears to be the Dose and not the Indication. Please review and update accordingly' answered with 'UPDATED ACCORDINGLY' (Site from DM).	Amanda Horn (b) (4) (b) (4)	05 Sep 2020 15:12:33
User entered 'ASTHMA' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	05 Sep 2020 15:12:14
User opened query 'Per CDM: This appears to be the Dose and not the Indication. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 12:30:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:23:15
User entered 'Asthma'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:39
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 14:23:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 14:23:33
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:23:33
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 14:23:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:23:15
User entered 'unknown'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:42
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:43
User entered 'unknown'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:45
User entered 'as needed (PRN)'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:48
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:52
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:54
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:04
User entered 'un UNK 2020'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:14
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:22
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:26:46

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:29
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:26:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:38:58
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CINNAMOMUM VERUM, PRODUCTSYNONYM: CINNAMON [CINNAMOMUM VERUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:19
Data point term sent to Coder	System	26 Aug 2020 18:28:22
User entered 'Cinnamon'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:58
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:09
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:05:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:05:13
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:23:17
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:40:10
User entered 'Supplement'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:42:52
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:32:35
User entered '500' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:00:48
User entered '1000'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:40:55
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:40:58
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:42:56
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:32:35
User entered 'twice daily (BID)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:00:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:10
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:15
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:22
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:24
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:39
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:47
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:32:35
User entered '2'	System	10 Nov 2020 16:00:48
User entered '1'	System	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:27:28

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:41:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:01:18
Data point term sent to Coder	System	26 Aug 2020 18:28:25
User entered 'Niacin'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:42:02
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:21
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:05:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:05:36
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:23:35
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:06
User entered 'supplement'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:11
User entered '500'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:14
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:16
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:24
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:31
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:37
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:39
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:44
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:28:06

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:42:47
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:28:06

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: TONICS, ATC: TONICS, PRODUCT: CURCUMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 05:51:43
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 05:51:43
Data point term sent to Coder	System	26 Aug 2020 18:29:29
User entered 'Curcumin with pepper'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:08
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:25
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:05:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:05:52
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:23:52
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:13
User entered 'Supplement'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:15
User entered '1000'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:17
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:20
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:25
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:30
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:32
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:42
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:45
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:05

FDA-CBER-2022-1614-3179995

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:43:48
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:29:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL, PRODUCTSYNONYM: OMEGA 3 [FISH OIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:44:11
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	03 Sep 2020 13:59:30
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 13:59:30
Data point term sent to Coder	System	03 Sep 2020 13:59:30
User entered 'OMEGA 3 COMPLEX (fish oil)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:59:22
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	03 Sep 2020 09:19:34
Data point term sent to Coder	System	26 Aug 2020 18:30:34
User entered 'Omega 3 complex'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:44:14
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:31
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:06:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:06:12
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:24:12
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:19
User entered 'Supplement'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:21
User entered '3000'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:22
User entered 'IU (IU)'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:24
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:29
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:44:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:34
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:37
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:40
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:44
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:46
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:29:49

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:02:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:02:18
Data point term sent to Coder	System	26 Aug 2020 18:31:38
User entered 'Fexofenadine'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:58
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:44:59
User entered 'Seasonal allergies'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:26:42
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:36
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:07:08
User entered '180' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:07:00
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:24:33
User entered '10'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:45:53
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:00
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:08
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:13
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:16
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:19
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:23
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:27
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:30:40

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:02:38
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 18:02:38
Data point term sent to Coder	System	26 Aug 2020 18:32:43
User entered 'Zyrtec'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:39
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:41
User entered 'Seasonal allergies'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:46
User entered '10'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:48
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:51
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:46:58
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:02
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:06
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:09
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:14
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:32:10

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:02:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:02:44
Data point term sent to Coder	System	26 Aug 2020 18:33:48
User entered 'Multivitamin'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:30
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:48
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:07:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:07:20
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:24:53
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:38
User entered 'Supplement'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:24:25
User entered 'unknown'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:41
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:24:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:24:25
User entered 'unknown'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:49
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:52
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:54
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:47:57
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:00
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:02
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:33:03

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:35:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:35:04
Data point term sent to Coder	System	18 Nov 2020 15:10:45
Coding entries removed.	(b) (4), (b) (6)	18 Nov 2020 15:09:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:48:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:13:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:13:45
Data point term sent to Coder	System	29 Sep 2020 16:13:12
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 16:12:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:21:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:21:34
Data point term sent to Coder	System	26 Aug 2020 18:35:54
User entered 'Meloxicam'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:16
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User closed query 'Per DM CLR: Please update the indication to reflect the type and/or location of JOINT PAIN (local or generalized). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:50:02
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:12:40
Query 'Per DM CLR: Please update the indication to reflect the type and/or location of JOINT PAIN (local or generalized). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:09:58
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:09:51
User entered 'JOINT PAIN (type and locaton unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:09:51
User opened query 'Per DM CLR: Please update the indication to reflect the type and/or location of JOINT PAIN (local or generalized). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:56:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:48:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:53
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:12:53
User entered 'Joint pain' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:12:47

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:25:12
User entered 'Antiinflammatory'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:31
User entered '15'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:33
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:34
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:43
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:45
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:48
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:51
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:34:56

FDA-CBER-2022-1614-3180087

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:53
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:34:56

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL, PRODUCTSYNONYM: CBD OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:12:38
Data point term sent to Coder	System	01 Sep 2020 14:27:39
User closed query 'DM-Coding: Please add active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	01 Sep 2020 14:27:25
Query 'DM-Coding: Please add active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'done' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 14:27:25
User entered 'CBD (CANNABIDOL OIL)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:27:01
Data point term sent to Coder	System	01 Sep 2020 14:26:38
User entered 'cannabidol oil' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:26:27
User opened query 'DM-Coding: Please add active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	26 Aug 2020 18:51:27
Data point term sent to Coder	System	26 Aug 2020 18:35:54
User entered 'CBD'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:50:03
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:52:57
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:12:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 16:12:07
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:25:28
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:05
User entered 'Supplement'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:07
User entered '15'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:13
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:09
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:17
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:20
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:22
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:26
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:50:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:29
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:30
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 18:35:30

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:15
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)	07 Oct 2020 16:13:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:13:50
Data point term sent to Coder	System	07 Oct 2020 14:11:02
User entered 'Ibuprofen'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:17
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:20
User entered 'Tendinitis bilateral wrists'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:24
User entered '400'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:26
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:29
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:32
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:33
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:10:02

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:36
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:10:02

FDA-CBER-2022-1614-3180119

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:41
User entered '01 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:43
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

FDA-CBER-2022-1614-3180121

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

FDA-CBER-2022-1614-3180122

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:46
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:10:02

FDA-CBER-2022-1614-3180123

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:51:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:10:02

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:02
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)	29 Oct 2020 16:48:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:48:42
Data point term sent to Coder	System	29 Oct 2020 16:47:50
User entered 'SEASONAL INFLUENZA VACCINATION'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:05
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:53:11
User entered 'PREVENTION OF SEASONAL INFLUENZA'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:13:20
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:12:30
User entered '1'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:13:21
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:12:30
User entered 'Other (OTHER)'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:12:30
User entered 'INJECTION'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:21
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:23
User entered empty.	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:30
User entered empty.	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:32
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:12:53
User entered '21 Oct 2020'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:35
User entered '0'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:36
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:37
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:12:53
User entered '21 Oct 2020'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:39
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User entered empty.	System	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User entered empty.	System	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:03
User entered empty.	System	29 Oct 2020 16:47:36

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:15:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:15:22
Data point term sent to Coder	System	05 Nov 2020 15:15:47
User entered 'Corticosteroid injection bilateral wrists'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:35
User entered 'Tendinitis bilateral wrists'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:39
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:40
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:42
User entered 'injection'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:47
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:50
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:52
User entered 'intraarticular'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:57
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:59
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:04
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:05
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User entered empty.	System	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User entered empty.	System	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:05
User entered empty.	System	05 Nov 2020 15:14:50

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 19:51:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 19:51:34
Data point term sent to Coder	System	08 Nov 2020 19:50:21
User entered 'PLAVIX'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:23
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:26
User entered 'PREVENTION OF STROKE'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:28
User entered '75'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:29
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:32
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:34
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:35
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:37
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:42
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

FDA-CBER-2022-1614-3180173

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:44
User entered '8 Nov 2020'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:46
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:38:31
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 17:38:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:56:47
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '11 Nov 2020' reason for change: New Information	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:04:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 17:38:31
User entered '22 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 17:38:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:56:49
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:56:50
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User entered '1'	System	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User entered '1'	System	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:08
User entered '804 (804)'	System	08 Nov 2020 19:49:34

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 23:49:37
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 Nov 2020 23:49:37
Data point term sent to Coder	System	08 Nov 2020 19:50:21
User entered 'VALACYCLOVIR'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:01
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:03
User entered 'TREATMENT OF BELL'S PALSY'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:05
User entered '1'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:07
User entered 'g (g)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:12
User entered 'three times daily (TID)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:15
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:17
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:21
User entered '8 Nov 2020'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:23
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 17:37:31
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 17:37:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:57:26
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '18 Nov 2020' reason for change: New Information	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 17:04:57
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 17:37:31
User entered '22 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 17:37:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:57:27
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:28
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User entered '3'	System	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User entered '1'	System	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:11
User entered '804 (804)'	System	08 Nov 2020 19:50:05

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 23:43:37
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 Nov 2020 23:43:37
Data point term sent to Coder	System	08 Nov 2020 19:51:21
User entered 'MEDROL'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:40
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:42
User entered 'TREATMENT OF BELL'S PALSY'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:44
User entered '4'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:48
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:51
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:53
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:56
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:57:58
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:36:54
User closed query 'Source indicates start/stop date of medrol is 11NOV2020. Please correct in EDC or clarify,' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:36:39
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
Query 'Source indicates start/stop date of medrol is 11NOV2020. Please correct in EDC or clarify,' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:20:06
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 18:19:58
User opened query 'Source indicates start/stop date of medrol is 11NOV2020. Please correct in EDC or clarify,' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 17:19:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 17:18:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:09
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:05
User entered '8 Nov 2020'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:08
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:19:29
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 17:36:43
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 17:36:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:11
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:37:02
User closed query 'Source indicates start/stop date of medrol is 11NOV2020. Please correct in EDC or clarify' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:36:57
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
Query 'Source indicates start/stop date of medrol is 11NOV2020. Please correct in EDC or clarify' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:20:12
User entered '11 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 18:19:58
User opened query 'Source indicates start/stop date of medrol is 11NOV2020. Please correct in EDC or clarify' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 17:19:23
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 17:36:43
User entered '22 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 17:36:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:15
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:58:16
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User entered '1'	System	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User entered '1'	System	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:17
User entered '804 (804)'	System	08 Nov 2020 19:50:46

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:52
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:09:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:09:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:02:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:02:40
Data point term sent to Coder	System	10 Nov 2020 16:17:40
User entered 'LOVENOX'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:50
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:00
User entered 'STROKE PREVENTION'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:03
User entered 'UNKNOWN'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:07
User entered 'Other (OTHER)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:13
User entered 'UNKNOWN AT THIS TIME'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:17
User entered 'unknown (UNKNOWN)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:26
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:28
User entered 'Other (OTHER)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:30
User entered 'UNKNOWN'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:22:20
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:11:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:10:34
User entered '06 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:10:36
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:22:29
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:11:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:10:39
User entered 'No (N)'	Haylee Rowe (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:22:31
User entered '07 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 19:05:01
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'Initially on hospitalization it was preventative in the case of a stroke that was later determined to be Bell's' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:34:07
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:33:25
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:33:25
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:49:55

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:46:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:49:48
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:49:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:12:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User entered empty.	System	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User entered empty.	System	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:19
User entered empty.	System	10 Nov 2020 16:16:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: IBUPROFEN;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:02:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:12:18
Data point term sent to Coder	System	10 Nov 2020 16:22:52
Data point term sent to Coder	System	10 Nov 2020 16:21:51
User entered 'ADVIL + TYLENOL COMBO'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:20
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:23
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 16:22:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 16:22:02
User entered 'GENERAL PAIN RELIEF' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:22:02
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 16:21:35
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:26
User entered '500'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:28
User entered 'mg (mg)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:31
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:34
User entered 'three times daily (TID)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:37
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:40
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:44
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:47
User entered 'UN UNK 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:50
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:12:56
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:07
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:09
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:21:35

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: PROVEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:37:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:37:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:13:28
Data point term sent to Coder	System	10 Nov 2020 16:23:54
User entered 'NUTRAVESTA PROVEN'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:03:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data changed' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:34:43
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:34:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:34:34
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:50:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:13:31
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:33
User entered 'SUPPLEMENT'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:36
User entered '2' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:43:58
User entered 'UNKNOWN' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:43:32
User entered '2'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:38
User entered 'capsule (CAPSULE)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:41
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:44
User entered 'once daily (QD)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:43:58
User entered 'twice daily (BID)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:43:32
User entered 'once daily (QD)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:47
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:51
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:13:56
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:00
User entered 'UN UNK 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:07
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

FDA-CBER-2022-1614-3180267

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:15
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

FDA-CBER-2022-1614-3180268

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:18
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:43:58
User entered '2'	System	10 Nov 2020 16:43:32
User entered '1'	System	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:23:51

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:26:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:26:38
Data point term sent to Coder	System	10 Nov 2020 16:25:56
User entered 'B COMPLEX'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:03:48
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:35:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:35:39
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'done' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:35:29
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:50:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:14:45
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:47
User entered 'SUPPLEMENT'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:49
User entered '50'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:50
User entered 'mg (mg)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:54
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:14:58
User entered 'once daily (QD)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:08
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:12
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:14
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:17
User entered 'UN UNK 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:21
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:24
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

FDA-CBER-2022-1614-3180285

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:28
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:15:30
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:24:57

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:24
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:42:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 16:42:39
Data point term sent to Coder	System	10 Nov 2020 16:26:58
User entered 'TURMERIC'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:03:58
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data changed' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:36:20
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:36:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 18:36:07
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:50:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:16:26
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:27
User entered 'SUPPLEMENT'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:31
User entered '500'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:34
User entered 'mg (mg)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:36
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:39
User entered 'twice daily (BID)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:41
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

FDA-CBER-2022-1614-3180298

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:43
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:45
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:49
User entered 'UN UNK 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:52
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:55
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:16:58
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:17:01
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:26:42

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:06
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 08:24:13
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 Nov 2020 08:24:13
Data point term sent to Coder	System	26 Nov 2020 01:38:05
Datapoint queued for coding (5163923).	System	26 Nov 2020 01:37:42
User entered 'PREDNISONE PACK' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 17:35:36
Data point term sent to Coder	System	23 Nov 2020 17:35:20
User entered 'Presnisone Pack'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:08
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:12
User entered 'Treatment of Bell's Palsy'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:16
User entered '10'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:18
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:19
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:22
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:35:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 17:35:36
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 17:35:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:34:44
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:24
User entered '6 Day Taper'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:28
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:31
User entered '16 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:34
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:36
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:37
User entered '22 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:21:39
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User entered empty.	System	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User entered empty.	System	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:23
User entered empty.	System	23 Nov 2020 17:34:44

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: PSEUDOEPHEDRINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:04:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:04:42
Data point term sent to Coder	System	14 Dec 2020 22:04:04
User entered 'PSEUDOEPHEDRINE HCL'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'NASAL CONGESTION'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '30'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '10 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '13 Dec 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Dec 2020 20:26:18
User entered '12 Dec 2020'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Dec 2020 22:03:21

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US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User entered empty.	System	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User entered empty.	System	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:19:27
User entered empty.	System	14 Dec 2020 22:03:21

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN LOW - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:42:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:42:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
Data point term sent to Coder	System	29 Mar 2021 18:28:33
User entered 'LOW DOSE ASPIRIN'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'THROMBOLYTIC PROPHYLAXIS' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered '81' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'mg (mg)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'other (OTHER)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '2X WEEKLY' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	29 Mar 2021 18:28:26
User entered '22 Mar 2021' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '0'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:46:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 18:28:26
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 18:27:33
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:46:43
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:27:33

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:46:43
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:22:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:54:31
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:28:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:27:45

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:14
User entered '06 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:55:44

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:16
User entered 'CT W/O CONTRAST'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:55:44

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:17
User entered 'Diagnostic (DIAGNOSTIC)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:55:44

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:46:43
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:20
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:55:44

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:30
User entered '06 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:57:01

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:31
User entered 'CHEST X-RAY'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:57:01

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:48:34
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 19:48:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:32
User entered 'Diagnostic (DIAGNOSTIC)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:57:01

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:46:43
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:04:34
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 16:57:01

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:48:53

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US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'MRI'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:48:53

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:48:53

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:46:43
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:48:53

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '25 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:30:59

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US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'MRI W/ CONTRAST'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:30:59

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US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:14:52
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Bell's Palsy is the AE for this procedure. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 14:54:11
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 21:00:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Adverse Event (AE)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:30:59

FDA-CBER-2022-1614-3180378

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:46:43
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:30:59

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '25 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:28

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'MRI W/O CONTRAST'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:28

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:21:29
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Bell's Palsy is the AE for this procedure. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 14:54:16
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 21:01:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Adverse Event (AE)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:28

FDA-CBER-2022-1614-3180382

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:46:43
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:28

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered '15 Mar 2021'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:51

FDA-CBER-2022-1614-3180384

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:46:43
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'CAROTID ARTERY DOPPLER'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:51

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:46:43
Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:21:35
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Bell's Palsy is the AE for this procedure. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 14:54:21
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 21:02:18
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered 'Adverse Event (AE)'	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:51

FDA-CBER-2022-1614-3180386

US3752245
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:46:43
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:09
User entered empty.	Haylee Rowe (b) (4) (b) (4)	29 Mar 2021 18:31:51

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:50
User entered '09/Nov/2020 09:47'	System	09 Nov 2020 14:47:25

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:51
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:04:42
User entered '12/Nov/2020 13:29'	System	12 Nov 2020 18:29:31

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:05:04
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 18:29:31

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '14/Dec/2020 11:42'	System	14 Dec 2020 16:42:17

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:26:14
User entered '1'	(b) (4), (b) (6)	14 Dec 2020 16:42:17

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '04/Jan/2021 18:26'	System	04 Jan 2021 18:26:26

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 17:28:37
User entered '1'	(b) (4), (b) (6)	04 Jan 2021 18:26:26

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '14/Jan/2021 12:28'	System	14 Jan 2021 17:28:49

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:03:17
User entered '1'	(b) (4), (b) (6)	14 Jan 2021 17:28:49

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

FDA-CBER-2022-1614-3180472

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

FDA-CBER-2022-1614-3180477

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (6)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '04/Feb/2021 08:03'	System	04 Feb 2021 13:03:28

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:47:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:03:28

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

FDA-CBER-2022-1614-3180491

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (7)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:33:27
User entered '26/Feb/2021 10:48'	System	26 Feb 2021 16:48:14

FDA-CBER-2022-1614-3180496

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 16:36:18
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:33:27
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:48:14

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

FDA-CBER-2022-1614-3180505

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (8)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:21:46
User entered '01/Apr/2021 12:29'	System	01 Apr 2021 16:29:20

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 16:36:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:21:46
User entered '1'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:29:20

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'USA-US113-2020-MRNA-1273-P301000009'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:13
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Death

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Yes (Y)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:23
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:26
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:28
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'No (N)'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:29
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Priyantha'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:26:31
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:47:09
User entered 'Wijewardane'	System	09 Nov 2020 14:46:07

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:04:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:26:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:36
User entered 'US'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:46:43
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	23 Apr 2021 16:36:41
User entered '8'	System	01 Apr 2021 16:29:20
Signature has been broken.	System	26 Feb 2021 16:48:14
User entered '7'	System	26 Feb 2021 16:48:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:04:12
User entered '6'	System	04 Feb 2021 13:03:28
User entered '5'	System	14 Jan 2021 17:28:49
User entered '4'	System	04 Jan 2021 18:26:26
User entered '3'	System	14 Dec 2020 16:42:17
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25

US3752245
Folder: SAE USA-US113-2020-MRNA-1273-P301000009
Form: Safety Report Form (9)
Generated On: 10 Jun 2021 09:46:43
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 23:36:26
User entered '23/Apr/2021 12:36'	System	23 Apr 2021 16:36:41

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:46:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 23:36:26
User entered '1'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:41