

US3752245 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:16:21

All time stamps listed in this document are displayed in GMT

US3752245

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:21

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

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)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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)	_____

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

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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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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)	

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Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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)	

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

Condition	PREVIOUS CVA
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)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	25 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:24 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 13:24
Height (<i>xxx.x</i>)	162.0 cm
Weight (<i>xxx.x</i>)	95.4 kg
BMI (<i>xxx.x</i>)	36.35117 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

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.

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

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
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

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	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

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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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

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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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:21

Collection date (<i>dd MMM yyyy</i>)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:41	25 AUG 2020 13:41
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:55

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 14:24

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: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 21:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 14:52

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:02

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: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 15:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

	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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

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.

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:21

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		

US3752245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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.

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 05:05

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 12:01

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

		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: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

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 ☒

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

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.

US3752245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 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: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 FEB 2021 00:01

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01 MAR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 MAR 2021 00:01

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08 MAR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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06 DEC 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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13 DEC 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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27 DEC 2021 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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03 JAN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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17 JAN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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31 JAN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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07 FEB 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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14 FEB 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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28 FEB 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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07 MAR 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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

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04 APR 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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

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11 APR 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

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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

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18 APR 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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25 APR 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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16 MAY 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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23 MAY 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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26 MAY 2022 00:01

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30 MAY 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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02 JUN 2022 00:01

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06 JUN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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13 JUN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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20 JUN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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23 JUN 2022 00:01

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27 JUN 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

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04 JUL 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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18 JUL 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

Date and time of submission

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01 AUG 2022 23:59

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

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

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

US3752245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752245

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:21

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3752245

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:16:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752245

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

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)	
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 ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

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	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

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.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:21

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

Yes ☒

No ☐

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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:21

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:21

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☒
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐
	Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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 (9)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intraocular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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 (16)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:16:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		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)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:21

	Intraocular	☐
	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:16:21

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:16:21

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	8 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)	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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		8 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)		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)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		8 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)		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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	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)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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 (25)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)

Generated On: 26 Nov 2020 11:16:21

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 ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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	☒

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:16:21

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	
Route of administration	6 DAY TAPER Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:16:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:16:21

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
06 NOV 2020	CT W/O CONTRAST	Diagnostic	
06 NOV 2020	CHEST X-RAY	Diagnostic	

US3752245

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:21

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

US3752245

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:21

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

Generated On: 26 Nov 2020 11:16:21

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)	2

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:21

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)	2
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

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:16:21

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)	2
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

US3752245

Folder: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:16:21

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)	2
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	

Audit

US3752245 (Prod: Baptist Health Center for Clinical Research)

US3752245

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:21

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3752245'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	25 Aug 2020 17:59:35

US3752245

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:57:13

US3752245

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	25 Aug 2020 17:59:36

US3752245

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 19:57:13

US3752245

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	25 Aug 2020 19:57:13

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	25 Aug 2020 17:59:37

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Age](#)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:21

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:06:46

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2020'	System	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:58:02

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	25 Aug 2020 17:59:36

US3752245

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:58:09

US3752245

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:58:09

US3752245

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:07:10

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2018'	System	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:07:29

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2018'	System	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:07:59

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:08:14

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2004'	System	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:08:39

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2010'	System	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:07

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:31

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:09:47

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1979'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '1979'	System	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '1979'	System	26 Aug 2020 18:10:17

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\23.0.	Coder Import (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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '1974'	System	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '1974'	System	26 Aug 2020 18:10:46

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2003'	System	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2003'	System	26 Aug 2020 18:11:02

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 18:11:18

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '1994'	System	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '1994'	System	26 Aug 2020 18:11:40

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: 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)	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)	06 Nov 2020 05:58:29
User coded data point as SOC: Investigations, HLG: 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)	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)	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, HLG: 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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2004'	System	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2004'	System	26 Aug 2020 18:11:57

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, 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) (b) (4)	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2017'	System	26 Aug 2020 18:12:14

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

Condition

Audit	User	Time (GMT)
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.	(b) (4), (b) (6)	29 Oct 2020 13:23:38
' answered with 'updated' (Site from DM).		
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:	(b) (4), (b) (6)	29 Oct 2020 13:23:31
Data Entry Error		
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.	(b) (4), (b) (6)	29 Oct 2020 06:02:45
' (Site from DM).		
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
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:13:16

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'un Jul 2020'	(b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:07:26

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:08:17

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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)	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:29

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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)	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:02:52

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

[Condition](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Haylee Rowe (b) (4) (b) (4)	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:04:21

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:24'	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:24'	System	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '162.0' cm	(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: 26 Nov 2020 11:16:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '95.4' kg	(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: 26 Nov 2020 11:16:21

BMI (xxx.x)

Audit	User	Time (GMT)
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

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 18:12:56

US3752245

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:21

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	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: 26 Nov 2020 11:16:21

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:21

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:14:19

US3752245

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:16:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:15:15

US3752245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:15:45

US3752245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	26 Aug 2020 18:15:45

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	25 Aug 2020 19:14:43

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '188125'	RWS_ENDPOINT ENDPOINT (b) (4) 	25 Aug 2020 19:14:43

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	25 Aug 2020 19:14:43

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:16:01

US3752245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Weight

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Weight](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 11:16:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:24'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:24'	System	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Route of measurement](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Height](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Weight](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Temperature (xxx.x)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Route of measurement](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	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: 26 Nov 2020 11:16:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 18:18:08
User entered empty.	System	26 Aug 2020 18:16:56

US3752245

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:37'	(b) (4), (b) (6)	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 14:37'	System	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 19:59:00

US3752245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:18:56

US3752245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:18:56

US3752245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:44'	(b) (4), (b) (6)	26 Aug 2020 18:18:56

US3752245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:44'	System	26 Aug 2020 18:18:56

US3752245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:19:10

US3752245

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:19:18

US3752245

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 18:19:18

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 14:57'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 18:22'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 2'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 3'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-a8f4-0fc63c4dc6'	System	27 Aug 2020 19:24:36
User entered 'Yes (Y)'	System	27 Aug 2020 19:24:36

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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-a8f4-0fc63c4dc6'	System	27 Aug 2020 19:24:36
User entered '97.7'	System	27 Aug 2020 19:24:36

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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-a8f4-0fc63c4dc6'	System	27 Aug 2020 19:24:36
User entered 'No (N)'	System	27 Aug 2020 19:24:36

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-a8f4-0fc63c4dc6'	System	27 Aug 2020 19:24:36
User entered '27 Aug 2020 14:24'	System	27 Aug 2020 19:24:36

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 4'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 14:57'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 18:22'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 2'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 3'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 4'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 14:57'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 18:22'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 2'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 3'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered 'Day 4'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:59:00

US3752245

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:02:21

US3752245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 14:02:21

US3752245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 14:02:21

US3752245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:02:21

US3752245

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:00:02

US3752245

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:00:02

US3752245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:01:33

US3752245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 14:01:33

US3752245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:01:33

US3752245

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:00:14

US3752245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:00:39

US3752245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 14:00:39

US3752245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:00:39

US3752245

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4) [REDACTED]	06 Oct 2020 18:35:29

US3752245

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 18:35:29

US3752245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	06 Oct 2020 18:36:06

US3752245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Lauren Evans (b) (4)	06 Oct 2020 18:36:06

US3752245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	06 Oct 2020 18:36:06

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 11:16:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:40'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:40'	System	07 Oct 2020 14:03:46

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Route of measurement](#)

Audit	User	Time (GMT)
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 System data change (Site from 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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from System).		07 Oct 2020 14:04:09
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	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) [REDACTED]	07 Oct 2020 14:03:46

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:03:46

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Temperature (xxx.x)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Route of measurement](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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: 26 Nov 2020 11:16:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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 System data change (Site from 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

US3752245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:05:10

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4) [REDACTED]	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Lauren Evans (b) (4) [REDACTED]	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:30'	Lauren Evans (b) (4)	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020 13:30'	System	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 18:36:45

US3752245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 14:05:39

US3752245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '06 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 14:05:39

US3752245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:59'	(b) (4), (b) (6)	07 Oct 2020 14:05:39

US3752245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:59'	System	07 Oct 2020 14:05:39

US3752245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(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: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '12:57'	(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: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(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: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 14:05:55

US3752245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 14:06:00

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 13:50'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 16:20'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 17:15'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 4'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 13:50'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 16:20'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 17:15'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 4'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Please select one response below

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 13:50'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 16:20'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 17:15'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 18:36:45
User entered 'Day 4'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

FATIGUE

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

CHILLS

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:36:45

US3752245

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:16:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:36:45

US3752245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 12:43:26

US3752245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 12:43:26

US3752245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 12:43:26

US3752245

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:05:00

US3752245

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:05:00

US3752245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:05:16

US3752245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 14:05:16

US3752245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:05:16

US3752245

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:05:21

US3752245

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:05:21

US3752245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 15:04:24

US3752245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 15:04:24

US3752245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:04:24

US3752245

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 15:04:29

US3752245

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:04:29

US3752245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:08:54

US3752245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
User entered '03 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:08:54

US3752245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 15:08:54

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:45'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 10:45'	System	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:09:23

US3752245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 10:47'	System	05 Nov 2020 15:09:50

US3752245

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:09:54

US3752245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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: '2020-11-08T13:23:46', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeae4d01fe3'	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: 26 Nov 2020 11:16:21

Have you been exposed to someone with 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: '2020-11-08T13:23:51', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeae4d01fe3'	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: 26 Nov 2020 11:16:21

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: '2020-11-08T13:23:55', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeae4d01fe3'	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: 26 Nov 2020 11:16:21

[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: '2020-11-08T13:24:05', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeae4d01fe3'	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: 26 Nov 2020 11:16:21

Please 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: '2020-11-08T13:24:12', User OID: 'PatientReportedOutcome (US3752245)', ODM File OID: '2a07d12b-0111-4378-8c9b-aeae4d01fe3'	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: 26 Nov 2020 11:16:21

[Date and time of submission](#)

Audit	User	Time (GMT)
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-aeae4d01fe3'	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: 26 Nov 2020 11:16:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 19:59:00
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 19:59:00

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 Oct 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: 26 Nov 2020 11:16:21

[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 Oct 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: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 Oct 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: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:33:26
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 17:33:26

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

Have you been exposed to someone with 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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

Please 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

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[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' User entered '22 Nov 2020 08:55:52'	System	22 Nov 2020 14:56:01
	System	22 Nov 2020 14:56:01

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

TIMEPOINT

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

TIMEPOINT

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

TIMEPOINT

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

TIMEPOINT

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

US3752245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:21

[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 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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[AEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Adverse event](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	08 Nov 2020 19:48:05

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	08 Nov 2020 19:48:05

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Severity](#)

Audit	User	Time (GMT)
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) (b) (4)	08 Nov 2020 19:48:05

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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)	08 Nov 2020 19:48:05

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:03:17
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)	08 Nov 2020 19:48:05

US3752245

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:21

[Serious Adverse Event 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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Nov 2020 19:48:05

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	10 Nov 2020 16:00:09
User entered 'once daily (QD)'	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:32:34
User entered 'Oral (ORAL)'	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:32:46
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:10
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:40
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:41
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:57
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:34:37
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:24
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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:58
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 Coding entries removed.	System Amanda Horn (b) (4) (b) (4)	05 Sep 2020 15:12:14 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 Coding entries removed.	System (b) (4), (b) (6) (b) (4)	01 Sep 2020 14:23:27 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
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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:26
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:38:22
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:42:44
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:13
User entered 'Supplement'	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:45
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
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)'	(b) (4), (b) (6)	03 Sep 2020 13:59:22
reason for change: Data Entry Error		
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)	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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:09
User entered '0'	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: 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 Coding entries removed.	System (b) (4), (b) (6)	18 Nov 2020 15:10:45 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 Coding entries removed.	System (b) (4), (b) (6)	29 Sep 2020 16:13:12 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
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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
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). DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:09:58
	(b) (4), (b) (6)	18 Nov 2020 15:09:51
User entered 'JOINT PAIN (type and location 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). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 08:56:28
	(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
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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:49:51
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:51:33
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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:51:36
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:51:43
User entered '0'	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:51:44
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:51:46
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
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)	29 Oct 2020 16:47:36

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
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)	29 Oct 2020 16:47:36

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:55:42
User entered 'injection'	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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)	08 Nov 2020 19:50:05

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (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.	(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)	08 Nov 2020 19:50:46
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:10:28
User entered 'Other (OTHER)'	Haylee Rowe (b) (4)	10 Nov 2020 16:16:57
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:10:36
User entered '0'	Haylee Rowe (b) (4)	10 Nov 2020 16:16:57
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	10 Nov 2020 16:21:35

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:12:40
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	10 Nov 2020 16:21:35
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: 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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:13:36
User entered '2' reason for change: Data Entry Error	Haylee Rowe (b) (4)	10 Nov 2020 16:43:58
User entered 'UNKNOWN' reason for change: Data Entry Error	Haylee Rowe (b) (4)	10 Nov 2020 16:43:32
User entered '2'	Haylee Rowe (b) (4)	10 Nov 2020 16:23:51

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:13:44
User entered 'once daily (QD)' reason for change:	Haylee Rowe (b) (4)	10 Nov 2020 16:43:58
Data Entry Error	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Haylee Rowe (b) (4)	10 Nov 2020 16:43:32
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	10 Nov 2020 16:23:51
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:14:18
User entered 'No (N)'	Haylee Rowe (b) (4)	10 Nov 2020 16:23:51
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:14:58
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	10 Nov 2020 16:24:57
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	10 Nov 2020 16:26:42

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:16:39
User entered 'twice daily (BID)'	Haylee Rowe (b) (4)	10 Nov 2020 16:26:42
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:16:43
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	10 Nov 2020 16:26:42
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:17:01
User entered 'No (N)'	Haylee Rowe (b) (4)	10 Nov 2020 16:26:42
	(b) (4)	

US3752245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[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: 26 Nov 2020 11:16:21

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'PREDNISONONE 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: 26 Nov 2020 11:16:21

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:34:44

US3752245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	10 Nov 2020 16:54:31
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	10 Nov 2020 16:28:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	10 Nov 2020 16:27:45

US3752245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:16:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:20
User entered empty.	Haylee Rowe (b) (4)	10 Nov 2020 16:55:44
	(b) (4)	

US3752245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:16:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: SAE USA-US113-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:21

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:21

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Nov 2020 18:29:31
User entered '1'	System	09 Nov 2020 14:47:25