

US3792016 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:48:55

All time stamps listed in this document are displayed in GMT

US3792016

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 21:54:20

Generated On: 10 Jun 2021 09:48:55

[Participant ID](#)

US3792016

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

US3792016

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3792016

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	CATARACTS, BILATERAL EYES
Start date (dd MMM yyyy)	01 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN JAN 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	ENDOMETREOSIS
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

US3792016

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	OSTEOARTHRITIS, BILATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	BILATERAL KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	DEGENERATIVE DISC DISEASE, CERVICAL, LUMBAR, THORACIC
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

US3792016

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Condition	NAUSEA, INTERMITTENT
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

US3792016

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:55 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 14:55
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	266.5 lb
BMI (<i>xxx.x</i>)	39.43746 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 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

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*) 12 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*) 12 AUG 2020

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

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:54:23

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 102166

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

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 14:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 16:08
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3792016

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 15:39 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 15:39

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 AUG 2020
Collection time (00:00-23:59)	15:12 (24 HR)
Collection date and time (derived)	12 AUG 2020 15:12

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:15	12 AUG 2020 15:15
Nasopharyngeal Swab 2	No		

US3792016

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp 12 AUG 2020 16:14

PC Open Date & Time 12 AUG 2020 15:59

PC Close Date & Time 12 AUG 2020 18:29

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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 97.6 °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	12 AUG 2020 19:35
PC Open Date & Time	12 AUG 2020 19:24
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 16:49

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:49

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:18

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 16:15

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

17 AUG 2020 15:21

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

97.2 °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

18 AUG 2020 13:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 16:15

PC Open Date & Time

12 AUG 2020 15:59

PC Close Date & Time

12 AUG 2020 18:29

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

12 AUG 2020 19:36

PC Open Date & Time

12 AUG 2020 19:24

PC Close Date & Time

13 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

13 AUG 2020 16:50

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

14 AUG 2020 14:50

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

15 AUG 2020 19:19

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

16 AUG 2020 16:15

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

17 AUG 2020 15:22

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

18 AUG 2020 13:12

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 16:16
PC Open Date & Time	12 AUG 2020 15:59
PC Close Date & Time	12 AUG 2020 18:29

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 19:37
PC Open Date & Time	12 AUG 2020 19:24
PC Close Date & Time	13 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 16:51
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2533

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 14:51
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

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 ☒

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:19
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2533

EAB) (1725)

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 16:16
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2533

EAB) (1725)

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 15:22
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2533

EAB) (1725)

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 13:12
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3792016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 10:52
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 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)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:56
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3792016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 11:18 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 11:18

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

US3792016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	9 SEP 2020 10:40

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	9 SEP 2020 10:45
Nasopharyngeal Swab 2	No		

US3792016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:23

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 11:46

PC Open Date & Time

09 SEP 2020 11:38

PC Close Date & Time

09 SEP 2020 14:08

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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 97.5 °F

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

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

PC Time Stamp	09 SEP 2020 21:01
PC Open Date & Time	09 SEP 2020 15:03
PC Close Date & Time	10 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:25

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 22:28

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

97.7 °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

12 SEP 2020 19:57

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

96.9 °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

14 SEP 2020 00:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

97.7 °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

14 SEP 2020 18:55

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

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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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

15 SEP 2020 21:57

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 11:47

PC Open Date & Time

09 SEP 2020 11:38

PC Close Date & Time

09 SEP 2020 14:08

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

09 SEP 2020 21:01

PC Open Date & Time

09 SEP 2020 15:03

PC Close Date & Time

10 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

10 SEP 2020 17:26

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

11 SEP 2020 22:29

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

12 SEP 2020 19:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

14 SEP 2020 00:49

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

14 SEP 2020 18:55

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

15 SEP 2020 21:57

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 11:47
PC Open Date & Time	09 SEP 2020 11:38
PC Close Date & Time	09 SEP 2020 14:08

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 21:02
PC Open Date & Time	09 SEP 2020 15:03
PC Close Date & Time	10 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

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 ☒

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:26
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

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 ☒

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 22:30
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

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 ☒

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:58
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 2533

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 00:50
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 2533

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:56
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

109 of 2533

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:58
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3792016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:54:24

Generated On: 10 Jun 2021 09:48:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:54:24

Generated On: 10 Jun 2021 09:48:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:48 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 10:48
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:54:24

Generated On: 10 Jun 2021 09:48:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3792016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:54:24

Generated On: 10 Jun 2021 09:48:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	11:09 (24 HR)
Collection date and time (derived)	6 OCT 2020 11:09

US3792016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:24

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 09:18:36

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 14:26:44

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 09:52:48

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 10:21:07

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 20:57:14

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 09:56:20

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 13:36:56

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 15:16:13

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 10:49:27

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 DEC 2020 12:36:25
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 13:10:00

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 13:54:44

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 23:27:27

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 08:36:23

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 11:27:50

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 09:14:03

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 08:10:52
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 00:39:47

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 00:33:02
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

26 FEB 2021 07:01:43

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 01:21:30

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 10:28:41

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 00:27:10

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 07:28:49

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 09:00:18

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 00:14:41

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 APR 2021 13:20:00
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 00:35:34

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 08:44:48

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3792016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:48:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 23:58:54

US3792016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:49 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 10:49
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

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.

US3792016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	11:05 (24 HR)
Collection date and time (derived)	8 MAR 2021 11:05

US3792016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 22:49:38

Generated On: 10 Jun 2021 09:48:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792016

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:49:38

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792016

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Date of Contact	19 APR 2021
Time of Contact	13:30
Date and Time of Contact (derived)	19 APR 2021 13:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 APR 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 APR 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 APR 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 APR 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 APR 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 APR 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 APR 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 APR 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 APR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 APR 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Date of Visit	21 APR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	21 APR 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Date of Contact	19 APR 2021
Time of Contact	13:30
Date and Time of Contact (derived)	19 APR 2021 13:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Date of Visit	13 APR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	13 APR 2021
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	HONOR HEALTH DEER VALLEY
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3792016

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 10 Jun 2021 09:48:55

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3792016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 05:39:32

Generated On: 10 Jun 2021 09:48:55

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

Visit date (dd MMM yyyy)	21 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
------------	--------

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 05:39:32

Generated On: 10 Jun 2021 09:48:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 APR 2021
Time of assessment (<i>00:00-23:59</i>)	13:05 (24 HR)
Vital Signs Date and Time (derived)	21 APR 2021 13:05
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 APR 2021

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

US3792016

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 APR 2021

US3792016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3792016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3792016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

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.

US3792016

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:48:55

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
--------------------	--

US3792016

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

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

Visit date (dd MMM yyyy)	7 JAN 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3792016

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Date of updated informed consent (dd MMM yyyy) 7 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 7 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3792016

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 JAN 2021

Collection time (00:00-23:59)

12:53 (24 HR)

Collection date and time (derived)

7 JAN 2021 12:53

US3792016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	12:58
Collection Date and Time (derived)	7 JAN 2021 12:58

US3792016

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 21:54:20

Generated On: 10 Jun 2021 09:48:55

Did the participant experience any adverse events?

Yes ☒
No ☐

If Yes, enter details on the Adverse Events form.

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

AEID

Adverse event

SINUS INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

17 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

AEID	USA-US057-2021-MRNA-1273-P30 1000003
Adverse event	PANCREATITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 APR 2021
Hospital Discharge Date (dd MMM yyyy)	19 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

PATIENT BEGAN
EXPERIENCING ABDOMINAL
PAIN ON 10APR2021 AT ~ 2230.
ON 13APR2021 PT CALLED PCP
WHO INSTRUCTED TO CALL
911. PT TRANSPORTED TO
HOSPITAL ON 13APR2021. MRCP
UNREMARKABLE, MILD
HEPATIC STEATOSIS, MILD
EDEMA AROUND PANCREATIC
TAIL CT REVEALED
PANCREATITIS. MRI DATE:
4/16/201 CT ABDOMEN/PELVIS
ON 4/13/21 REVEALED
INFLAMMATION OF PANCREAS

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

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 21:54:21

Generated On: 10 Jun 2021 09:48:55

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

Yes ☒

No ☐

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

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication NUCUNTA

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication PROMETHAZINE

Prophylaxis Yes ☒
No ☐

Indication INTERMITTENT NAUSEA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication DEGENERATIVE DISC DISEASE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication DEGENERATIVE DISC DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication GUIFENISEN

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication CARDURA

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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 ☐

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US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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EAB) (1725)

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication AMOXICILLIN 500 MG -
CLAVULANIC ACID 125

Prophylaxis Yes ☐
No ☒

Indication SINUS INFECTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication PANCRELIPASE

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

Dose per administration 60000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication PANCREATITIS

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 ☐

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EAB) (1725)

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 20:41:36

Generated On: 10 Jun 2021 09:48:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 05:39:31

Generated On: 10 Jun 2021 09:48:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 OCT 2020	RIGHT CATARACT REMOVAL	Medical History	
21 OCT 2020	LEFT CATARACT REMOVAL	Medical History	
13 APR 2021	CT ABDOMEN AND PELVIS WITH CONTRAST	Adverse Event	
17 APR 2021	UPPER ENDOSCOPY	Adverse Event	

US3792016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:48:55

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

US3792016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:48:55

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 ☐

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

SAEID	USA-US057-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

SAEID	USA-US057-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 12:46
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

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

SAEID	USA-US057-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 17:59
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

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

SAEID	USA-US057-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/APR/2021 14:18
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

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 15:12:11

Generated On: 10 Jun 2021 09:48:55

SAEID	USA-US057-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	29/APR/2021 07:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3792016 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3792016

Form: Participant Creation

Generated On: 10 Jun 2021 09:48:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'US3792016'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:59:28

US3792016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:23:45

US3792016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:59:29

US3792016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	12 Aug 2020 22:23:45

US3792016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'SCRN'	System	12 Aug 2020 22:23:45

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:59:30

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '64'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'YEARS'	System	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '64'	System	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Female (F)'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'I'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:24:12

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered '12 Aug 2020'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Aug 2020'	System	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2020'	System	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered 'Amendment 2 (2)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:24:32

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 22:01:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 21:59:29

US3792016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'I'	System	12 Aug 2020 22:24:37

US3792016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:24:37

US3792016

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:48:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:24:48

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 23:32:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 23:32:12
Data point term sent to Coder	System	13 Aug 2020 22:59:33
User entered 'Cataracts, bilateral eyes'	Norma Frederick (b) (4)	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '01 Jul 2020'	Norma Frederick (b) (4)	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jul 2020'	System	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2020'	System	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 22:59:24

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:10
Data point term sent to Coder	System	13 Aug 2020 23:00:34
User entered 'Hypertension'	Norma Frederick (b) (4)	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '01 Feb 2020'	Norma Frederick (b) (4)	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Feb 2020'	System	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2020'	System	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 22:59:56

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:10
Data point term sent to Coder	System	13 Aug 2020 23:00:36
User entered 'Acid Reflux'	Norma Frederick (b) (4)	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un Jan 2008'	Norma Frederick (b) (4)	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 2008'	System	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2008'	System	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:00:19

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:10
Data point term sent to Coder	System	13 Aug 2020 23:01:36
User entered 'Endometreosis'	Norma Frederick (b) (4)	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1986'	Norma Frederick (b) (4)	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1992'	Norma Frederick (b) (4)	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1986'	System	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1986'	System	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1992'	System	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1992'	System	13 Aug 2020 23:01:11

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:02:37
Data point term sent to Coder	System	13 Aug 2020 23:01:38
User entered 'hysterectomy'	Norma Frederick (b) (4)	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1992'	Norma Frederick (b) (4)	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1992'	Norma Frederick (b) (4)	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1992'	System	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1992'	System	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1992'	System	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1992'	System	13 Aug 2020 23:01:35

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:04:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:04:11
Data point term sent to Coder	System	13 Aug 2020 23:02:41
User entered 'Fibromyalgia'	Norma Frederick (b) (4)	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1992'	Norma Frederick (b) (4)	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1992'	System	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1992'	System	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:02:18

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:04:10
Data point term sent to Coder	System	13 Aug 2020 23:03:43
User entered 'osteoarthritis, bilateral knees'	Norma Frederick (b) (4)	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 2000'	Norma Frederick (b) (4)	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 2013'	Norma Frederick (b) (4)	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 2000'	System	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2000'	System	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 2013'	System	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2013'	System	13 Aug 2020 23:03:25

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:06:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:06:07
Data point term sent to Coder	System	13 Aug 2020 23:04:46
User entered 'Bilateral Knee Replacement'	Norma Frederick (b) (4)	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 2013'	Norma Frederick (b) (4)	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 2013'	Norma Frederick (b) (4)	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 2013'	System	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2013'	System	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 2013'	System	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2013'	System	13 Aug 2020 23:04:02

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 05:42:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 05:42:15
Data point term sent to Coder	System	13 Aug 2020 23:04:47
User entered 'degenerative disc disease, cervical, lumbar, thoracic'	Norma Frederick (b) (4)	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 2012'	Norma Frederick (b) (4)	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 2012'	System	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '2012'	System	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:04:41

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:07:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 23:07:08
Data point term sent to Coder	System	13 Aug 2020 23:05:49
User entered 'migraine headaches'	Norma Frederick (b) (4)	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1992'	Norma Frederick (b) (4)	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1992'	System	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1992'	System	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:05:01

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Per MM, please review and update the term to final diagnosis' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:17:51
Query 'Per MM, please review and update the term to final diagnosis' answered with 'this is final diagnosis' (Site from DM).	Bettie Corcoran (b) (4) (b) (4)	22 Sep 2020 16:53:16
User opened query 'Per MM, please review and update the term to final diagnosis' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 23:33:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:14:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:14:31
Data point term sent to Coder	System	13 Aug 2020 23:05:49
User entered 'nausea, intermittent'	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'un UNK 1992'	Norma Frederick (b) (4)	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'Jan 1992'	System	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '1992'	System	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered empty.	System	13 Aug 2020 23:05:26

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '14:55'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered '12 Aug 2020 14:55'	System	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '69' in	(b) (4)	
	Norma Frederick (b) (4)	12 Aug 2020 22:25:50
DataPoint set to visible.	(b) (4)	
	System	12 Aug 2020 22:24:37

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '266.5' lb	Norma Frederick (b) (4)	12 Aug 2020 22:25:50
DataPoint set to visible.	System	12 Aug 2020 22:24:37

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
Amendment Manager: User entered '39.43746'	System	16 Sep 2020 23:54:34
User entered '39.4'	System	12 Aug 2020 22:25:50
DataPoint set to visible.	System	12 Aug 2020 22:24:37

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'kg/m2'	System	12 Aug 2020 22:25:50
DataPoint set to visible.	System	12 Aug 2020 22:24:37

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Aug 2020 20:00:29
User entered '97.5' F	Norma Frederick (b) (4)	12 Aug 2020 22:25:50
	(b) (4)	

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty; reason for change Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	31 Aug 2020 20:00:29
User entered 'Oral (Oral)'	(b) (4)	
	Norma Frederick (b) (4)	12 Aug 2020 22:25:50
	(b) (4)	

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Aug 2020 20:00:29
User entered '83'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'bpm'	System	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Aug 2020 20:00:29
User entered '16'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'breaths/min'	System	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Aug 2020 20:00:29
User entered '119'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'mmHg'	System	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	31 Aug 2020 20:00:29
User entered '84'	Norma Frederick (b) (4)	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User entered 'mmHg'	System	12 Aug 2020 22:25:50

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20

US3792016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20

US3792016

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:26:07

US3792016

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 15:47:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 17:42:20
User entered '12 Aug 2020'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:26:07

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Surgically sterile (SURGICALLY STERILE)'	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:26:49

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'I'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:20
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:27:48

US3792016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:37

US3792016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:28:37

US3792016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:37

US3792016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'VISIT1'	System	12 Aug 2020 22:28:37

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:14:17

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:02:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:02:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 22:14:17
User entered '102166' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:14:17

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 22:14:17

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:57

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:57

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:57

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:57

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	12 Aug 2020 22:28:57

US3792016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:55

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Scarlett Hammett (b) (4)	26 Sep 2020 00:25:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:55:12

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 22:17:56
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 22:17:56
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 22:17:56
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 22:17:56
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '14:55'	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '12 Aug 2020 14:55'	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:24:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:24:40
User entered '97.5' F reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:24:40
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Aug 2020 22:31:40
User entered empty.	System	12 Aug 2020 22:31:40
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:24:40
User entered 'Oral (Oral)' reason for change: Data Entry Error	System	13 Aug 2020 22:24:40
User opened query 'Data is required. Please provide.' (Site from System).	Norma Frederick (b) (4)	13 Aug 2020 22:24:40
User entered empty.	(b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:24:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:24:40
User entered '83' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:24:40
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Aug 2020 22:31:40
User entered empty.	System	12 Aug 2020 22:31:40
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'bpm'	System	13 Aug 2020 22:24:40
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:24:40
Query 'Data is required. Please provide.' answered by System	System	13 Aug 2020 22:24:40
data change (Site from System).		
User entered '16' reason for change: Data Entry	Norma Frederick (b) (4)	13 Aug 2020 22:24:40
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 22:31:40
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'breaths/min'	System	13 Aug 2020 22:24:40
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:24:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:24:40
User entered '119' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:24:40
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Aug 2020 22:31:40
User entered empty.	System	12 Aug 2020 22:31:40
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	13 Aug 2020 22:24:40
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:24:40
Query 'Data is required. Please provide.' answered by System	System	13 Aug 2020 22:24:40
data change (Site from System).		
User entered '84' reason for change: Data Entry	Norma Frederick (b) (4)	13 Aug 2020 22:24:40
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 22:31:40
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	13 Aug 2020 22:24:40
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 22:17:56
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 22:17:56
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 22:25:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:25:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 22:31:40
User entered empty.	System	12 Aug 2020 22:31:40
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	13 Aug 2020 22:25:53
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL VITALS CAN BE TAKEN 30 MIN POST' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:14:35
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL VITALS CAN BE TAKEN 30 MIN POST' (Site from System).	Norma Frederick (b) (4)	13 Aug 2020 22:27:58
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '16:08' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:25:53
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '12 Aug 2020 16:08'	System	13 Aug 2020 22:25:53
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:27:09
User entered '97.5' F reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:27:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
User entered empty.	System	13 Aug 2020 22:25:53
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:27:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:27:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
User entered empty.	System	13 Aug 2020 22:31:40
	Norma Frederick (b) (4)	
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:27:09
User entered '84' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:27:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
User entered empty.	System	13 Aug 2020 22:25:53
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'bpm'	System	13 Aug 2020 22:27:09
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:27:09
User entered '16' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:27:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
User entered empty.	System	13 Aug 2020 22:25:53
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'breaths/min'	System	13 Aug 2020 22:27:09
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:27:09
User entered '108' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:27:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
User entered empty.	System	13 Aug 2020 22:25:53
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	13 Aug 2020 22:27:09
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:27:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Aug 2020 22:27:09
User entered '79' reason for change: Data Entry Error	Norma Frederick (b) (4)	13 Aug 2020 22:27:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 22:25:53
User entered empty.	System	13 Aug 2020 22:25:53
	Norma Frederick (b) (4)	12 Aug 2020 22:31:40
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	13 Aug 2020 22:27:09
User entered empty.	System	12 Aug 2020 22:31:40

US3792016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	31 Aug 2020 22:55:01
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:32:00
	(b) (4)	

US3792016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	31 Aug 2020 22:55:01
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:32:00

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020'	Norma Frederick (b) (4)	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '15:39'	Norma Frederick (b) (4)	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '12 Aug 2020 15:39'	System	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'ONCE'	System	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 22:43:01

US3792016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 22:32:56

US3792016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020'	Norma Frederick (b) (4)	13 Aug 2020 22:32:56

US3792016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '15:12'	Norma Frederick (b) (4)	13 Aug 2020 22:32:56

US3792016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '12 Aug 2020 15:12'	System	13 Aug 2020 22:32:56

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '12 Aug 2020'	Norma Frederick (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '15:15'	Norma Frederick (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '12 Aug 2020 15:15'	System	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered empty.	System	13 Aug 2020 22:33:42

US3792016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	13 Aug 2020 22:33:51

US3792016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	13 Aug 2020 22:33:51

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:13:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6cb2904f-b21b-4af3-bf9c-f043b1e5bd3d' User entered 'Yes (Y)'	System	12 Aug 2020 23:14:25
	System	12 Aug 2020 23:14:25

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:13:59', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6cb2904f-b21b-4af3-bf9c-f043b1e5bd3d' User entered '97.5'	System	12 Aug 2020 23:14:25
	System	12 Aug 2020 23:14:25

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:14:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6cb2904f-b21b-4af3-bf9c-f043b1e5bd3d'	System	12 Aug 2020 23:14:25
User entered 'No (N)'	System	12 Aug 2020 23:14:25

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:14:19', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6cb2904f-b21b-4af3-bf9c-f043b1e5bd3d'	System	12 Aug 2020 23:14:25
User entered '12 Aug 2020 16:14'	System	12 Aug 2020 23:14:25

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 15:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 18:29'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:35:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'b4009776-d2c0-4a3a-a3a5-29c8b6f9d528'	System	13 Aug 2020 02:35:56
User entered 'Yes (Y)'	System	13 Aug 2020 02:35:56

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:35:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'b4009776-d2c0-4a3a-a3a5-29c8b6f9d528' User entered '97.6'	System	13 Aug 2020 02:35:56
	System	13 Aug 2020 02:35:56

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:35:38', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'b4009776-d2c0-4a3a-a3a5-29c8b6f9d528'	System	13 Aug 2020 02:35:56
User entered 'No (N)'	System	13 Aug 2020 02:35:56

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:35:53', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'b4009776-d2c0-4a3a-a3a5-29c8b6f9d528'	System	13 Aug 2020 02:35:56
User entered '12 Aug 2020 19:35'	System	13 Aug 2020 02:35:56

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 19:24'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 2'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:49:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5ad16aa3-eac9-45ca-b1b0-b988defdb15a' User entered 'Yes (Y)'	System	13 Aug 2020 23:49:28
	System	13 Aug 2020 23:49:28

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:49:17', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5ad16aa3-eac9-45ca-b1b0-b988defdb15a' User entered '98.0'	System	13 Aug 2020 23:49:28
	System	13 Aug 2020 23:49:28

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:49:21', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5ad16aa3-eac9-45ca-b1b0-b988defdb15a'	System	13 Aug 2020 23:49:28
User entered 'No (N)'	System	13 Aug 2020 23:49:28

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:49:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5ad16aa3-eac9-45ca-b1b0-b988defdb15a' User entered '13 Aug 2020 16:49'	System	13 Aug 2020 23:49:28
	System	13 Aug 2020 23:49:28

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 3'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:49:22', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff1a1092-d451-44ad-a82c-c320dbb4232c' User entered 'Yes (Y)'	System	14 Aug 2020 21:49:59
	System	14 Aug 2020 21:49:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:49:45', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff1a1092-d451-44ad-a82c-c320dbb4232c' User entered '97.5'	System	14 Aug 2020 21:49:59
	System	14 Aug 2020 21:49:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:49:49', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff1a1092-d451-44ad-a82c-c320dbb4232c'	System	14 Aug 2020 21:49:59
User entered 'No (N)'	System	14 Aug 2020 21:49:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:49:57', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff1a1092-d451-44ad-a82c-c320dbb4232c' User entered '14 Aug 2020 14:49'	System	14 Aug 2020 21:49:59
	System	14 Aug 2020 21:49:59

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 4'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:18:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '2310dde2-b5e8-4113-b6b6-81102784929a'	System	16 Aug 2020 02:18:48
User entered 'Yes (Y)'	System	16 Aug 2020 02:18:48

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:18:35', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '2310dde2-b5e8-4113-b6b6-81102784929a' User entered '97.0'	System	16 Aug 2020 02:18:48
	System	16 Aug 2020 02:18:48

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:18:38', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '2310dde2-b5e8-4113-b6b6-81102784929a'	System	16 Aug 2020 02:18:48
User entered 'No (N)'	System	16 Aug 2020 02:18:48

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:18:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '2310dde2-b5e8-4113-b6b6-81102784929a'	System	16 Aug 2020 02:18:48
User entered '15 Aug 2020 19:18'	System	16 Aug 2020 02:18:48

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 5'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:05', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01292a7f-18ed-44f9-8c62-717696172667' User entered 'Yes (Y)'	System	16 Aug 2020 23:15:22
	System	16 Aug 2020 23:15:22

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:12', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01292a7f-18ed-44f9-8c62-717696172667' User entered '98.3'	System	16 Aug 2020 23:15:22
	System	16 Aug 2020 23:15:22

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:15', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01292a7f-18ed-44f9-8c62-717696172667' User entered 'No (N)'	System	16 Aug 2020 23:15:22
	System	16 Aug 2020 23:15:22

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:19', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01292a7f-18ed-44f9-8c62-717696172667' User entered '16 Aug 2020 16:15'	System	16 Aug 2020 23:15:22
	System	16 Aug 2020 23:15:22

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 6'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:21:39', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cfca7fff-e1cb-42a6-aca9-284b82967465'	System	17 Aug 2020 22:21:53
User entered 'Yes (Y)'	System	17 Aug 2020 22:21:53

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:21:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cfca7fff-e1cb-42a6-aca9-284b82967465'	System	17 Aug 2020 22:21:53
User entered '98.6'	System	17 Aug 2020 22:21:53

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:21:47', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cfca7fff-e1cb-42a6-aca9-284b82967465'	System	17 Aug 2020 22:21:53
User entered 'No (N)'	System	17 Aug 2020 22:21:53

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:21:51', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cfca7fff-e1cb-42a6-aca9-284b82967465'	System	17 Aug 2020 22:21:53
User entered '17 Aug 2020 15:21'	System	17 Aug 2020 22:21:53

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 7'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:10:33', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '05b7c3e9-fae2-4a74-8446-b2fe62456a50' User entered 'Yes (Y)'	System	18 Aug 2020 20:11:29
	System	18 Aug 2020 20:11:29

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:11:05', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '05b7c3e9-fae2-4a74-8446-b2fe62456a50' User entered '97.2'	System	18 Aug 2020 20:11:29
	System	18 Aug 2020 20:11:29

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:11:15', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '05b7c3e9-fae2-4a74-8446-b2fe62456a50'	System	18 Aug 2020 20:11:29
User entered 'No (N)'	System	18 Aug 2020 20:11:29

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:11:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '05b7c3e9-fae2-4a74-8446-b2fe62456a50' User entered '18 Aug 2020 13:11'	System	18 Aug 2020 20:11:29
	System	18 Aug 2020 20:11:29

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:14:56', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5e8361d3-797c-405c-a4fe-867473db412d' User entered 'None (1)'	System	12 Aug 2020 23:15:26
	System	12 Aug 2020 23:15:26

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:03', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5e8361d3-797c-405c-a4fe-867473db412d' User entered 'No (N)'	System	12 Aug 2020 23:15:26
	System	12 Aug 2020 23:15:26

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5e8361d3-797c-405c-a4fe-867473db412d' User entered 'No (N)'	System	12 Aug 2020 23:15:26
	System	12 Aug 2020 23:15:26

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5e8361d3-797c-405c-a4fe-867473db412d' User entered 'None (1)'	System	12 Aug 2020 23:15:26
	System	12 Aug 2020 23:15:26

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:24', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5e8361d3-797c-405c-a4fe-867473db412d' User entered '12 Aug 2020 16:15'	System	12 Aug 2020 23:15:26
	System	12 Aug 2020 23:15:26

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 15:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 18:29'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:36:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa0b60ba-39fe-4ecd-adfb-b2d2829e56ac'	System	13 Aug 2020 02:36:53
User entered 'None (1)'	System	13 Aug 2020 02:36:53

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:36:26', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa0b60ba-39fe-4ecd-adfb-b2d2829e56ac'	System	13 Aug 2020 02:36:53
User entered 'No (N)'	System	13 Aug 2020 02:36:53

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:36:35', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa0b60ba-39fe-4ecd-adfb-b2d2829e56ac'	System	13 Aug 2020 02:36:53
User entered 'No (N)'	System	13 Aug 2020 02:36:53

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:36:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa0b60ba-39fe-4ecd-adfb-b2d2829e56ac'	System	13 Aug 2020 02:36:53
User entered 'None (1)'	System	13 Aug 2020 02:36:53

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:36:49', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa0b60ba-39fe-4ecd-adfb-b2d2829e56ac'	System	13 Aug 2020 02:36:53
User entered '12 Aug 2020 19:36'	System	13 Aug 2020 02:36:53

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 19:24'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 2'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:49:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c57a16d5-2767-4dac-80d5-3ac5c9ef268c'	System	13 Aug 2020 23:50:35
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 23:50:35

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c57a16d5-2767-4dac-80d5-3ac5c9ef268c' User entered 'No (N)'	System	13 Aug 2020 23:50:35
	System	13 Aug 2020 23:50:35

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:11', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c57a16d5-2767-4dac-80d5-3ac5c9ef268c' User entered 'No (N)'	System	13 Aug 2020 23:50:35
	System	13 Aug 2020 23:50:35

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:24', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c57a16d5-2767-4dac-80d5-3ac5c9ef268c' User entered 'None (1)'	System	13 Aug 2020 23:50:35
	System	13 Aug 2020 23:50:35

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:33', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c57a16d5-2767-4dac-80d5-3ac5c9ef268c' User entered '13 Aug 2020 16:50'	System	13 Aug 2020 23:50:35
	System	13 Aug 2020 23:50:35

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 3'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '38e7bb52-4ab8-4bd2-a0d3-e9f0f93b8e7c'	System	14 Aug 2020 21:50:38
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 21:50:38

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '38e7bb52-4ab8-4bd2-a0d3-e9f0f93b8e7c' User entered 'No (N)'	System	14 Aug 2020 21:50:38
	System	14 Aug 2020 21:50:38

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:26', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '38e7bb52-4ab8-4bd2-a0d3-e9f0f93b8e7c' User entered 'No (N)'	System	14 Aug 2020 21:50:38
	System	14 Aug 2020 21:50:38

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:29', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '38e7bb52-4ab8-4bd2-a0d3-e9f0f93b8e7c' User entered 'None (1)'	System	14 Aug 2020 21:50:38
	System	14 Aug 2020 21:50:38

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:34', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '38e7bb52-4ab8-4bd2-a0d3-e9f0f93b8e7c' User entered '14 Aug 2020 14:50'	System	14 Aug 2020 21:50:38
	System	14 Aug 2020 21:50:38

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 4'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:02', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8bcaadc8-cc90-46b6-8ec2-52d50142f8d8'	System	16 Aug 2020 02:19:18
User entered 'None (1)'	System	16 Aug 2020 02:19:18

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:05', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8bcaadc8-cc90-46b6-8ec2-52d50142f8d8'	System	16 Aug 2020 02:19:18
User entered 'No (N)'	System	16 Aug 2020 02:19:18

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8bcaadc8-cc90-46b6-8ec2-52d50142f8d8'	System	16 Aug 2020 02:19:18
User entered 'No (N)'	System	16 Aug 2020 02:19:18

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:12', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8bcaadc8-cc90-46b6-8ec2-52d50142f8d8'	System	16 Aug 2020 02:19:18
User entered 'None (1)'	System	16 Aug 2020 02:19:18

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8bcaadc8-cc90-46b6-8ec2-52d50142f8d8'	System	16 Aug 2020 02:19:18
User entered '15 Aug 2020 19:19'	System	16 Aug 2020 02:19:18

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 5'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ed7ab476-979e-4f4f-b4f3-ac4ed261e526'	System	16 Aug 2020 23:15:42
User entered 'None (1)'	System	16 Aug 2020 23:15:42

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:29', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ed7ab476-979e-4f4f-b4f3-ac4ed261e526'	System	16 Aug 2020 23:15:42
User entered 'No (N)'	System	16 Aug 2020 23:15:42

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:32', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ed7ab476-979e-4f4f-b4f3-ac4ed261e526'	System	16 Aug 2020 23:15:42
User entered 'No (N)'	System	16 Aug 2020 23:15:42

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:35', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ed7ab476-979e-4f4f-b4f3-ac4ed261e526'	System	16 Aug 2020 23:15:42
User entered 'None (1)'	System	16 Aug 2020 23:15:42

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ed7ab476-979e-4f4f-b4f3-ac4ed261e526'	System	16 Aug 2020 23:15:42
User entered '16 Aug 2020 16:15'	System	16 Aug 2020 23:15:42

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 6'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:02', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'af284079-4e7b-4361-b316-c14a4ea23c2e'	System	17 Aug 2020 22:22:28
User entered 'None (1)'	System	17 Aug 2020 22:22:28

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:06', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'af284079-4e7b-4361-b316-c14a4ea23c2e'	System	17 Aug 2020 22:22:28
User entered 'No (N)'	System	17 Aug 2020 22:22:28

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:10', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'af284079-4e7b-4361-b316-c14a4ea23c2e'	System	17 Aug 2020 22:22:28
User entered 'No (N)'	System	17 Aug 2020 22:22:28

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:22', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'af284079-4e7b-4361-b316-c14a4ea23c2e' User entered 'None (1)'	System	17 Aug 2020 22:22:28
	System	17 Aug 2020 22:22:28

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'af284079-4e7b-4361-b316-c14a4ea23c2e' User entered '17 Aug 2020 15:22'	System	17 Aug 2020 22:22:28
	System	17 Aug 2020 22:22:28

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 7'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:11:37', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c096572b-cfb4-46f7-8fd7-88ebc62aaba1' User entered 'None (1)'	System	18 Aug 2020 20:12:15
	System	18 Aug 2020 20:12:15

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:11:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c096572b-cfb4-46f7-8fd7-88ebc62aaba1' User entered 'No (N)'	System	18 Aug 2020 20:12:15
	System	18 Aug 2020 20:12:15

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:11:48', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c096572b-cfb4-46f7-8fd7-88ebc62aaba1' User entered 'No (N)'	System	18 Aug 2020 20:12:15
	System	18 Aug 2020 20:12:15

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c096572b-cfb4-46f7-8fd7-88ebc62aaba1'	System	18 Aug 2020 20:12:15
User entered 'None (1)'	System	18 Aug 2020 20:12:15

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c096572b-cfb4-46f7-8fd7-88ebc62aaba1' User entered '18 Aug 2020 13:12'	System	18 Aug 2020 20:12:15
	System	18 Aug 2020 20:12:15

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:30', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'None (0)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:35', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'None (0)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:39', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'None (0)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'None (0)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:15:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'None (0)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:16:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'None (0)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:16:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered 'No (N)'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T16:16:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '3a4d39aa-45e5-4254-b7d7-2c56f8ca960f' User entered '12 Aug 2020 16:16'	System	12 Aug 2020 23:16:18
	System	12 Aug 2020 23:16:18

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 15:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 18:29'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:36:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'None (0)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:03', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'None (0)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'None (0)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:10', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'None (0)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'None (0)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:17', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'None (0)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered 'No (N)'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-12T19:37:32', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ccc50c2a-67bc-4152-86df-cc3c354946ae' User entered '12 Aug 2020 19:37'	System	13 Aug 2020 02:37:33
	System	13 Aug 2020 02:37:33

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Aug 2020 19:24'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 2'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'None (0)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'None (0)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:47', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'None (0)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:50', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'None (0)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:53', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'None (0)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:50:56', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'None (0)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:51:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered 'No (N)'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-13T16:51:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cf96260f-4259-4e32-8eb2-e2e97fe3aafb' User entered '13 Aug 2020 16:51'	System	13 Aug 2020 23:51:09
	System	13 Aug 2020 23:51:09

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 3'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:41', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'None (0)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'None (0)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:46', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'None (0)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:48', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'None (0)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:51', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'None (0)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'None (0)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:50:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered 'No (N)'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-14T14:51:03', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '714e05db-dbaf-408b-9500-ce8825e878b5' User entered '14 Aug 2020 14:51'	System	14 Aug 2020 21:51:06
	System	14 Aug 2020 21:51:06

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 4'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'None (0)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:28', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'None (0)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:32', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'None (0)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:35', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'None (0)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:38', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'None (0)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:41', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'None (0)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:46', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered 'No (N)'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-15T19:19:50', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '21f55d76-9956-4d77-b8ce-074987f2d4f4' User entered '15 Aug 2020 19:19'	System	16 Aug 2020 02:19:52
	System	16 Aug 2020 02:19:52

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 5'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:46', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered 'None (0)'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:48', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered 'None (0)'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered 'None (0)'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:55', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered 'None (0)'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:15:57', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered 'None (0)'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:16:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered 'None (0)'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:16:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6'	System	16 Aug 2020 23:16:10
User entered 'No (N)'	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-16T16:16:09', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '8e24b862-fcc2-44b6-9de2-5ff7d363a8e6' User entered '16 Aug 2020 16:16'	System	16 Aug 2020 23:16:10
	System	16 Aug 2020 23:16:10

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 6'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:31', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'None (0)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:33', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'None (0)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'None (0)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:38', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'None (0)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'None (0)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'None (0)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:47', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered 'No (N)'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-17T15:22:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '24f51a7b-13df-41b9-a4b1-f36ce5f7d0c9' User entered '17 Aug 2020 15:22'	System	17 Aug 2020 22:22:55
	System	17 Aug 2020 22:22:55

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 7'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:14', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'None (0)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'None (0)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'None (0)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'None (0)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'None (0)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:28', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'None (0)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:34', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered 'No (N)'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-08-18T13:12:39', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc7b5d23-48a0-48bc-8c6e-7c4b4b433f2f' User entered '18 Aug 2020 13:12'	System	18 Aug 2020 20:12:42
	System	18 Aug 2020 20:12:42

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 22:43:01

US3792016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	19 Aug 2020 17:25:06

US3792016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '19 Aug 2020'	Ann Marie Milliken	19 Aug 2020 17:25:06

US3792016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	19 Aug 2020 17:25:06

US3792016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	19 Aug 2020 17:25:06

US3792016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	19 Aug 2020 17:25:12

US3792016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	19 Aug 2020 17:25:12

US3792016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	26 Aug 2020 22:54:48

US3792016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '26 Aug 2020'	Ann Marie Milliken	26 Aug 2020 22:54:48

US3792016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	26 Aug 2020 22:54:48

US3792016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	26 Aug 2020 22:54:48

US3792016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	26 Aug 2020 22:54:54

US3792016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	26 Aug 2020 22:54:54

US3792016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	02 Sep 2020 19:10:05

US3792016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '2 Sep 2020'	Ann Marie Milliken (b) (4)	02 Sep 2020 19:10:05

US3792016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	02 Sep 2020 19:10:05

US3792016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	02 Sep 2020 19:10:05

US3792016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	02 Sep 2020 19:10:11

US3792016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	02 Sep 2020 19:10:11

US3792016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Sep 2020 17:42:20

US3792016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020'	Norma Frederick (b) (4)	09 Sep 2020 17:42:20

US3792016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	09 Sep 2020 17:42:20

US3792016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'VISIT2'	System	09 Sep 2020 17:42:20

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '10:52'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '9 Sep 2020 10:52'	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '97.7' F	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '77'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'bpm'	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '16'	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'breaths/min'	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 01:28:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 01:28:26
User entered '112' reason for change: Data Entry Error	Norma Frederick (b) (4)	10 Sep 2020 01:28:26
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 01:24:08
User entered empty.	System	10 Sep 2020 01:24:08
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	10 Sep 2020 01:28:26
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 01:28:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 01:28:26
User entered '67' reason for change: Data Entry Error	Norma Frederick (b) (4)	10 Sep 2020 01:28:26
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 01:24:08
User entered empty.	System	10 Sep 2020 01:24:08
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	10 Sep 2020 01:28:26
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 01:29:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 01:29:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 01:24:08
User entered empty.	System	10 Sep 2020 01:24:08
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '11:56' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '9 Sep 2020 11:56'	System	10 Sep 2020 01:29:40
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '72' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'bpm'	System	10 Sep 2020 01:29:40
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'breaths/min'	System	10 Sep 2020 01:29:40
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '120' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	10 Sep 2020 01:29:40
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '77' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:29:40
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	10 Sep 2020 01:24:08
	(b) (4)	

US3792016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	10 Sep 2020 01:29:40
User entered empty.	System	10 Sep 2020 01:24:08

US3792016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Sep 2020 18:37:29

US3792016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020'	Norma Frederick (b) (4)	09 Sep 2020 18:37:29

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020'	Norma Frederick (b) (4)	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '11:18'	Norma Frederick (b) (4)	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '9 Sep 2020 11:18'	System	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'ONCE'	System	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 18:38:38

US3792016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Sep 2020 17:43:26

US3792016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020'	Norma Frederick (b) (4)	09 Sep 2020 17:43:26

US3792016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '10:40'	Norma Frederick (b) (4)	09 Sep 2020 17:43:26

US3792016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '9 Sep 2020 10:40'	System	09 Sep 2020 17:43:26

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '9 Sep 2020'	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '10:45'	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '9 Sep 2020 10:45'	System	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'No (N)'	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered empty.	System	09 Sep 2020 18:37:48

US3792016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Sep 2020 18:37:56

US3792016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	09 Sep 2020 18:37:56

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:46:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '156034e8-7aad-455b-9c1d-2b4499452fc9' User entered 'Yes (Y)'	System	09 Sep 2020 18:46:47
	System	09 Sep 2020 18:46:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:46:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '156034e8-7aad-455b-9c1d-2b4499452fc9' User entered '96.5'	System	09 Sep 2020 18:46:47
	System	09 Sep 2020 18:46:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:46:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '156034e8-7aad-455b-9c1d-2b4499452fc9' User entered 'No (N)'	System	09 Sep 2020 18:46:47
	System	09 Sep 2020 18:46:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:46:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '156034e8-7aad-455b-9c1d-2b4499452fc9' User entered '09 Sep 2020 11:46'	System	09 Sep 2020 18:46:47
	System	09 Sep 2020 18:46:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 11:38'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 14:08'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:00:14', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '766acf5e-9b74-4ad5-934e-f8b83f6c043c' User entered 'Yes (Y)'	System	10 Sep 2020 04:01:23
	System	10 Sep 2020 04:01:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:00:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '766acf5e-9b74-4ad5-934e-f8b83f6c043c' User entered '97.5'	System	10 Sep 2020 04:01:23
	System	10 Sep 2020 04:01:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:00:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '766acf5e-9b74-4ad5-934e-f8b83f6c043c' User entered 'No (N)'	System	10 Sep 2020 04:01:23
	System	10 Sep 2020 04:01:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:03', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '766acf5e-9b74-4ad5-934e-f8b83f6c043c' User entered '09 Sep 2020 21:01'	System	10 Sep 2020 04:01:23
	System	10 Sep 2020 04:01:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 15:03'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 2'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:24:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '97a7eb8c-1e5a-48f9-bfc9-1499ca2dc04e' User entered 'Yes (Y)'	System	11 Sep 2020 00:25:25
	System	11 Sep 2020 00:25:25

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:12', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '97a7eb8c-1e5a-48f9-bfc9-1499ca2dc04e' User entered '97.0'	System	11 Sep 2020 00:25:25
	System	11 Sep 2020 00:25:25

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:18', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '97a7eb8c-1e5a-48f9-bfc9-1499ca2dc04e'	System	11 Sep 2020 00:25:25
User entered 'No (N)'	System	11 Sep 2020 00:25:25

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:22', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '97a7eb8c-1e5a-48f9-bfc9-1499ca2dc04e' User entered '10 Sep 2020 17:25'	System	11 Sep 2020 00:25:25
	System	11 Sep 2020 00:25:25

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 3'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:28:26', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff917d0b-020b-49fa-8bd0-f9ad997106a5' User entered 'Yes (Y)'	System	12 Sep 2020 05:28:47
	System	12 Sep 2020 05:28:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:28:33', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff917d0b-020b-49fa-8bd0-f9ad997106a5' User entered '96.5'	System	12 Sep 2020 05:28:47
	System	12 Sep 2020 05:28:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:28:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff917d0b-020b-49fa-8bd0-f9ad997106a5'	System	12 Sep 2020 05:28:47
User entered 'No (N)'	System	12 Sep 2020 05:28:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:28:45', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ff917d0b-020b-49fa-8bd0-f9ad997106a5' User entered '11 Sep 2020 22:28'	System	12 Sep 2020 05:28:47
	System	12 Sep 2020 05:28:47

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 4'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:57:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01dfdb4c-ca9f-4a27-9119-fc53182023ea' User entered 'Yes (Y)'	System	13 Sep 2020 02:57:48
	System	13 Sep 2020 02:57:48

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:57:30', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01dfdb4c-ca9f-4a27-9119-fc53182023ea' User entered '97.7'	System	13 Sep 2020 02:57:48
	System	13 Sep 2020 02:57:48

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:57:39', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01dfdb4c-ca9f-4a27-9119-fc53182023ea' User entered 'No (N)'	System	13 Sep 2020 02:57:48
	System	13 Sep 2020 02:57:48

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:57:45', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '01dfdb4c-ca9f-4a27-9119-fc53182023ea' User entered '12 Sep 2020 19:57'	System	13 Sep 2020 02:57:48
	System	13 Sep 2020 02:57:48

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 5'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:48:22', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1c3823b0-2729-4125-99ed-279f1e30c04c' User entered 'Yes (Y)'	System	14 Sep 2020 07:48:43
	System	14 Sep 2020 07:48:43

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:48:34', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1c3823b0-2729-4125-99ed-279f1e30c04c' User entered '96.9'	System	14 Sep 2020 07:48:43
	System	14 Sep 2020 07:48:43

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:48:37', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1c3823b0-2729-4125-99ed-279f1e30c04c' User entered 'No (N)'	System	14 Sep 2020 07:48:43
	System	14 Sep 2020 07:48:43

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:48:41', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1c3823b0-2729-4125-99ed-279f1e30c04c' User entered '14 Sep 2020 00:48'	System	14 Sep 2020 07:48:43
	System	14 Sep 2020 07:48:43

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 6'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:05', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '210f110d-8e93-4ddf-96a7-4de4e1fb409f' User entered 'Yes (Y)'	System	15 Sep 2020 01:55:31
	System	15 Sep 2020 01:55:31

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:10', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '210f110d-8e93-4ddf-96a7-4de4e1fb409f' User entered '97.7'	System	15 Sep 2020 01:55:31
	System	15 Sep 2020 01:55:31

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '210f110d-8e93-4ddf-96a7-4de4e1fb409f' User entered 'No (N)'	System	15 Sep 2020 01:55:31
	System	15 Sep 2020 01:55:31

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '210f110d-8e93-4ddf-96a7-4de4e1fb409f' User entered '14 Sep 2020 18:55'	System	15 Sep 2020 01:55:31
	System	15 Sep 2020 01:55:31

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 7'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3df685c-0f4d-4ad9-ae17-3f038f6a93d1' User entered 'Yes (Y)'	System	16 Sep 2020 04:57:23
	System	16 Sep 2020 04:57:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3df685c-0f4d-4ad9-ae17-3f038f6a93d1' User entered '97.7'	System	16 Sep 2020 04:57:23
	System	16 Sep 2020 04:57:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3df685c-0f4d-4ad9-ae17-3f038f6a93d1' User entered 'No (N)'	System	16 Sep 2020 04:57:23
	System	16 Sep 2020 04:57:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:21', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3df685c-0f4d-4ad9-ae17-3f038f6a93d1' User entered '15 Sep 2020 21:57'	System	16 Sep 2020 04:57:23
	System	16 Sep 2020 04:57:23

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:46:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '73af49cb-77fb-405a-bcd1-9acc22e0d5d2'	System	09 Sep 2020 18:47:19
User entered 'None (1)'	System	09 Sep 2020 18:47:19

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '73af49cb-77fb-405a-bcd1-9acc22e0d5d2'	System	09 Sep 2020 18:47:19
User entered 'No (N)'	System	09 Sep 2020 18:47:19

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '73af49cb-77fb-405a-bcd1-9acc22e0d5d2'	System	09 Sep 2020 18:47:19
User entered 'No (N)'	System	09 Sep 2020 18:47:19

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:12', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '73af49cb-77fb-405a-bcd1-9acc22e0d5d2'	System	09 Sep 2020 18:47:19
User entered 'None (1)'	System	09 Sep 2020 18:47:19

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:18', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '73af49cb-77fb-405a-bcd1-9acc22e0d5d2'	System	09 Sep 2020 18:47:19
User entered '09 Sep 2020 11:47'	System	09 Sep 2020 18:47:19

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 11:38'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 14:08'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0011d724-522d-4a91-854a-519726cb9aa0'	System	10 Sep 2020 04:01:52
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 04:01:52

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:30', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0011d724-522d-4a91-854a-519726cb9aa0' User entered 'No (N)'	System	10 Sep 2020 04:01:52
	System	10 Sep 2020 04:01:52

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:32', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0011d724-522d-4a91-854a-519726cb9aa0' User entered 'No (N)'	System	10 Sep 2020 04:01:52
	System	10 Sep 2020 04:01:52

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:38', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0011d724-522d-4a91-854a-519726cb9aa0'	System	10 Sep 2020 04:01:52
User entered 'None (1)'	System	10 Sep 2020 04:01:52

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0011d724-522d-4a91-854a-519726cb9aa0' User entered '09 Sep 2020 21:01'	System	10 Sep 2020 04:01:52
	System	10 Sep 2020 04:01:52

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 15:03'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 2'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:30', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '58213603-3754-4e7a-a6ed-10bbfa0260a2'	System	11 Sep 2020 00:26:05
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:26:05

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '58213603-3754-4e7a-a6ed-10bbfa0260a2' User entered 'No (N)'	System	11 Sep 2020 00:26:05
	System	11 Sep 2020 00:26:05

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '58213603-3754-4e7a-a6ed-10bbfa0260a2' User entered 'No (N)'	System	11 Sep 2020 00:26:05
	System	11 Sep 2020 00:26:05

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:25:53', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '58213603-3754-4e7a-a6ed-10bbfa0260a2'	System	11 Sep 2020 00:26:05
User entered 'None (1)'	System	11 Sep 2020 00:26:05

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:01', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '58213603-3754-4e7a-a6ed-10bbfa0260a2' User entered '10 Sep 2020 17:26'	System	11 Sep 2020 00:26:05
	System	11 Sep 2020 00:26:05

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 3'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:01', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ea6f44e8-8246-4273-8bb3-81d8adcbf937'	System	12 Sep 2020 05:29:48
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 05:29:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ea6f44e8-8246-4273-8bb3-81d8adcbf937' User entered 'No (N)'	System	12 Sep 2020 05:29:48
	System	12 Sep 2020 05:29:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ea6f44e8-8246-4273-8bb3-81d8adcbf937'	System	12 Sep 2020 05:29:48
User entered 'No (N)'	System	12 Sep 2020 05:29:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:35', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ea6f44e8-8246-4273-8bb3-81d8adcbf937'	System	12 Sep 2020 05:29:48
User entered 'None (1)'	System	12 Sep 2020 05:29:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ea6f44e8-8246-4273-8bb3-81d8adcbf937'	System	12 Sep 2020 05:29:48
User entered '11 Sep 2020 22:29'	System	12 Sep 2020 05:29:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 4'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7e3a86b6-e6ab-4194-a7e2-66fe01921c59'	System	13 Sep 2020 02:58:24
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 02:58:24

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7e3a86b6-e6ab-4194-a7e2-66fe01921c59' User entered 'No (N)'	System	13 Sep 2020 02:58:24
	System	13 Sep 2020 02:58:24

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:11', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7e3a86b6-e6ab-4194-a7e2-66fe01921c59'	System	13 Sep 2020 02:58:24
User entered 'No (N)'	System	13 Sep 2020 02:58:24

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:15', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7e3a86b6-e6ab-4194-a7e2-66fe01921c59'	System	13 Sep 2020 02:58:24
User entered 'None (1)'	System	13 Sep 2020 02:58:24

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7e3a86b6-e6ab-4194-a7e2-66fe01921c59'	System	13 Sep 2020 02:58:24
User entered '12 Sep 2020 19:58'	System	13 Sep 2020 02:58:24

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 5'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:21', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa065fcd-7d7b-40e1-88ed-5a98f5a339c2'	System	14 Sep 2020 07:49:48
User entered 'None (1)'	System	14 Sep 2020 07:49:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:24', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa065fcd-7d7b-40e1-88ed-5a98f5a339c2'	System	14 Sep 2020 07:49:48
User entered 'No (N)'	System	14 Sep 2020 07:49:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa065fcd-7d7b-40e1-88ed-5a98f5a339c2'	System	14 Sep 2020 07:49:48
User entered 'No (N)'	System	14 Sep 2020 07:49:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:32', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa065fcd-7d7b-40e1-88ed-5a98f5a339c2'	System	14 Sep 2020 07:49:48
User entered 'None (1)'	System	14 Sep 2020 07:49:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'aa065fcd-7d7b-40e1-88ed-5a98f5a339c2'	System	14 Sep 2020 07:49:48
User entered '14 Sep 2020 00:49'	System	14 Sep 2020 07:49:48

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 6'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:37', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c803793a-76e2-4545-9200-22bb3177d468'	System	15 Sep 2020 01:55:57
User entered 'None (1)'	System	15 Sep 2020 01:55:57

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c803793a-76e2-4545-9200-22bb3177d468' User entered 'No (N)'	System	15 Sep 2020 01:55:57
	System	15 Sep 2020 01:55:57

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:45', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c803793a-76e2-4545-9200-22bb3177d468' User entered 'No (N)'	System	15 Sep 2020 01:55:57
	System	15 Sep 2020 01:55:57

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c803793a-76e2-4545-9200-22bb3177d468'	System	15 Sep 2020 01:55:57
User entered 'None (1)'	System	15 Sep 2020 01:55:57

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:55:56', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c803793a-76e2-4545-9200-22bb3177d468' User entered '14 Sep 2020 18:55'	System	15 Sep 2020 01:55:57
	System	15 Sep 2020 01:55:57

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 7'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:32', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7152cef1-147a-4388-84e3-5e3257e8a0a9'	System	16 Sep 2020 04:57:49
User entered 'None (1)'	System	16 Sep 2020 04:57:49

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:34', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7152cef1-147a-4388-84e3-5e3257e8a0a9' User entered 'No (N)'	System	16 Sep 2020 04:57:49
	System	16 Sep 2020 04:57:49

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7152cef1-147a-4388-84e3-5e3257e8a0a9' User entered 'No (N)'	System	16 Sep 2020 04:57:49
	System	16 Sep 2020 04:57:49

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7152cef1-147a-4388-84e3-5e3257e8a0a9'	System	16 Sep 2020 04:57:49
User entered 'None (1)'	System	16 Sep 2020 04:57:49

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:46', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '7152cef1-147a-4388-84e3-5e3257e8a0a9' User entered '15 Sep 2020 21:57'	System	16 Sep 2020 04:57:49
	System	16 Sep 2020 04:57:49

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'None (0)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'None (0)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:28', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'None (0)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:30', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'None (0)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:34', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'None (0)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:37', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'None (0)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered 'No (N)'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T11:47:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '0b91e04f-0319-4828-9d09-4bec64b30854' User entered '09 Sep 2020 11:47'	System	09 Sep 2020 18:47:45
	System	09 Sep 2020 18:47:45

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 11:38'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 14:08'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:49', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'None (0)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'None (0)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:01:55', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'None (0)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:02:01', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'None (0)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:02:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'None (0)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:02:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'None (0)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:02:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered 'No (N)'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-09T21:02:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae066451-f788-4a62-854e-86a037e481ba' User entered '09 Sep 2020 21:02'	System	10 Sep 2020 04:02:54
	System	10 Sep 2020 04:02:54

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '09 Sep 2020 15:03'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 2'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:06', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf' User entered 'None (0)'	System	11 Sep 2020 00:26:49
	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:09', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf' User entered 'None (0)'	System	11 Sep 2020 00:26:49
	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf' User entered 'None (0)'	System	11 Sep 2020 00:26:49
	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:26', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf'	System	11 Sep 2020 00:26:49
User entered 'No interference with activity (1)'	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:29', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf' User entered 'None (0)'	System	11 Sep 2020 00:26:49
	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf' User entered 'None (0)'	System	11 Sep 2020 00:26:49
	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf'	System	11 Sep 2020 00:26:49
User entered 'No (N)'	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-10T17:26:47', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e5bcc4a1-f35e-44fb-89d5-f8b533c7dfaf' User entered '10 Sep 2020 17:26'	System	11 Sep 2020 00:26:49
	System	11 Sep 2020 00:26:49

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 3'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:49', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'None (0)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'None (0)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:29:56', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'None (0)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:30:02', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'None (0)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:30:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'None (0)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:30:10', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'None (0)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:30:15', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered 'No (N)'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-11T22:30:21', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '23efb655-edb8-4151-8be0-450414f5c673' User entered '11 Sep 2020 22:30'	System	12 Sep 2020 05:30:25
	System	12 Sep 2020 05:30:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 4'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:29', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'None (0)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:33', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'None (0)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'None (0)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'None (0)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:43', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'None (0)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:46', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'None (0)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:49', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered 'No (N)'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-12T19:58:53', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '20c1bcee-2ee3-463e-bc05-c98bf9df7d29' User entered '12 Sep 2020 19:58'	System	13 Sep 2020 02:58:57
	System	13 Sep 2020 02:58:57

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 5'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:50', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered 'None (0)'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered 'None (0)'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:49:57', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered 'None (0)'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:50:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered 'None (0)'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:50:03', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered 'None (0)'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:50:05', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered 'None (0)'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:50:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422'	System	14 Sep 2020 07:50:15
User entered 'No (N)'	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T00:50:12', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '28ed9bff-cd06-4d2d-a850-709df7560422' User entered '14 Sep 2020 00:50'	System	14 Sep 2020 07:50:15
	System	14 Sep 2020 07:50:15

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 6'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'None (0)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:02', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'None (0)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'None (0)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:06', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'None (0)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:08', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'None (0)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:11', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'None (0)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:14', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered 'No (N)'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-14T18:56:21', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'de3be993-6696-4536-a0ad-c77a2f3ae1b5' User entered '14 Sep 2020 18:56'	System	15 Sep 2020 01:56:25
	System	15 Sep 2020 01:56:25

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	09 Sep 2020 18:38:38
User entered 'Day 7'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'None (0)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'None (0)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:57:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'None (0)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:58:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'None (0)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:58:05', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'None (0)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:58:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'None (0)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:58:11', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered 'No (N)'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-09-15T21:58:15', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '72d58a5d-e687-4ae8-b722-106c3a80dc88' User entered '15 Sep 2020 21:58'	System	16 Sep 2020 04:58:17
	System	16 Sep 2020 04:58:17

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:38:38

US3792016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:38:38

US3792016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	16 Sep 2020 17:52:01

US3792016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '16 Sep 2020'	Ann Marie Milliken	16 Sep 2020 17:52:01

US3792016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	16 Sep 2020 17:52:01

US3792016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	16 Sep 2020 17:52:01

US3792016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	16 Sep 2020 17:53:57

US3792016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	16 Sep 2020 17:53:57

US3792016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	23 Sep 2020 17:34:28

US3792016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '23 Sep 2020'	Ann Marie Milliken	23 Sep 2020 17:34:28

US3792016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	23 Sep 2020 17:34:28

US3792016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	Ann Marie Milliken (b) (4)	23 Sep 2020 17:34:28

US3792016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	23 Sep 2020 17:34:34

US3792016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	23 Sep 2020 17:34:34

US3792016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	01 Oct 2020 17:41:01

US3792016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '1 Oct 2020'	Ann Marie Milliken	01 Oct 2020 17:41:01

US3792016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	01 Oct 2020 17:41:01

US3792016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	01 Oct 2020 17:41:01

US3792016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	01 Oct 2020 17:41:07

US3792016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	01 Oct 2020 17:41:07

US3792016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Oct 2020 17:56:10

US3792016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '6 Oct 2020'	Norma Frederick (b) (4)	06 Oct 2020 17:56:10

US3792016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	06 Oct 2020 17:56:10

US3792016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'VISIT3'	System	06 Oct 2020 17:56:10

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '6 Oct 2020'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '10:48'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '6 Oct 2020 10:48'	System	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '97.6' F	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered empty.	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '88'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'bpm'	System	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '16'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'breaths/min'	System	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '136'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '82'	Norma Frederick (b) (4)	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'mmHg'	System	06 Oct 2020 17:57:17

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46

US3792016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46

US3792016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Oct 2020 17:57:24

US3792016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '6 Oct 2020'	Norma Frederick (b) (4)	06 Oct 2020 17:57:24

US3792016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	07 Oct 2020 00:57:51

US3792016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '6 Oct 2020'	Norma Frederick (b) (4)	07 Oct 2020 00:57:51

US3792016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered '11:09'	Norma Frederick (b) (4)	07 Oct 2020 00:57:51

US3792016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered '6 Oct 2020 11:09'	System	07 Oct 2020 00:57:51

US3792016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:24
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Oct 2020 17:57:34

US3792016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	06 Oct 2020 17:57:34

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 64'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-13T09:18:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '506ea4a9-4ccf-4502-a8c8-507bfcacd325'	System	13 Oct 2020 16:18:38
User entered 'No (N)'	System	13 Oct 2020 16:18:38

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-13T09:18:31', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '506ea4a9-4ccf-4502-a8c8-507bfcacd325'	System	13 Oct 2020 16:18:38
User entered 'No (N)'	System	13 Oct 2020 16:18:38

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-13T09:18:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '506ea4a9-4ccf-4502-a8c8-507bfcacd325' User entered '13 Oct 2020 09:18:36'	System	13 Oct 2020 16:18:38
	System	13 Oct 2020 16:18:38

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 71'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-20T14:26:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '044edb82-69a1-4e6a-9dcd-3a4b38863f67'	System	20 Oct 2020 21:26:49
User entered 'No (N)'	System	20 Oct 2020 21:26:49

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-20T14:26:18', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '044edb82-69a1-4e6a-9dcd-3a4b38863f67'	System	20 Oct 2020 21:26:49
User entered 'No (N)'	System	20 Oct 2020 21:26:49

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-20T14:26:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '044edb82-69a1-4e6a-9dcd-3a4b38863f67' User entered '20 Oct 2020 14:26:44'	System	20 Oct 2020 21:26:49
	System	20 Oct 2020 21:26:49

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 78'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-26T09:52:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae0b8d2e-cd4c-4b0f-a584-4ae7be64c903'	System	26 Oct 2020 16:52:50
User entered 'No (N)'	System	26 Oct 2020 16:52:50

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-26T09:52:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae0b8d2e-cd4c-4b0f-a584-4ae7be64c903'	System	26 Oct 2020 16:52:50
User entered 'No (N)'	System	26 Oct 2020 16:52:50

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-10-26T09:52:48', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae0b8d2e-cd4c-4b0f-a584-4ae7be64c903' User entered '26 Oct 2020 09:52:48'	System	26 Oct 2020 16:52:50
	System	26 Oct 2020 16:52:50

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 92'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-10T10:20:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6c061b08-49da-4fe3-90e8-72996811d75c' User entered 'No (N)'	System	10 Nov 2020 17:21:10
	System	10 Nov 2020 17:21:10

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-10T10:21:02', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6c061b08-49da-4fe3-90e8-72996811d75c' User entered 'No (N)'	System	10 Nov 2020 17:21:10
	System	10 Nov 2020 17:21:10

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-10T10:21:07', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '6c061b08-49da-4fe3-90e8-72996811d75c' User entered '10 Nov 2020 10:21:07'	System	10 Nov 2020 17:21:10
	System	10 Nov 2020 17:21:10

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered 'Day 99'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-17T20:56:45', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'dc0e5f0f-0a91-4d1b-be54-da1abf199173'	System	18 Nov 2020 03:57:18
User entered 'No (N)'	System	18 Nov 2020 03:57:18

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-17T20:56:56', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'dc0e5f0f-0a91-4d1b-be54-da1abf199173'	System	18 Nov 2020 03:57:18
User entered 'No (N)'	System	18 Nov 2020 03:57:18

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-17T20:57:14', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'dc0e5f0f-0a91-4d1b-be54-da1abf199173' User entered '17 Nov 2020 20:57:14'	System	18 Nov 2020 03:57:18
	System	18 Nov 2020 03:57:18

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 22:43:01

US3792016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:32:15
Data entry locked.	System	12 Aug 2020 22:43:01
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 22:43:01

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-22T09:56:06', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'be81cca1-18ef-405e-b021-a668dcb7cc6e'	System	22 Nov 2020 16:56:24
User entered 'No (N)'	System	22 Nov 2020 16:56:24

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-22T09:56:10', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'be81cca1-18ef-405e-b021-a668dcb7cc6e' User entered 'No (N)'	System	22 Nov 2020 16:56:24

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-22T09:56:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'be81cca1-18ef-405e-b021-a668dcb7cc6e' User entered '22 Nov 2020 09:56:20'	System	22 Nov 2020 16:56:24
	System	22 Nov 2020 16:56:24

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-27T13:36:46', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '381db2a1-b8b9-4733-b715-3840158372bd' User entered 'No (N)'	System	27 Nov 2020 20:36:58
	System	27 Nov 2020 20:36:58

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-27T13:36:51', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '381db2a1-b8b9-4733-b715-3840158372bd' User entered 'No (N)'	System	27 Nov 2020 20:36:58

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-11-27T13:36:56', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '381db2a1-b8b9-4733-b715-3840158372bd' User entered '27 Nov 2020 13:36:56'	System	27 Nov 2020 20:36:58
	System	27 Nov 2020 20:36:58

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-04T15:16:06', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '9859b6ee-f9b8-4fd4-b61c-7326db95828a' User entered 'No (N)'	System	04 Dec 2020 22:16:16
	System	04 Dec 2020 22:16:16

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-04T15:16:10', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '9859b6ee-f9b8-4fd4-b61c-7326db95828a' User entered 'No (N)'	System	04 Dec 2020 22:16:16

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-04T15:16:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '9859b6ee-f9b8-4fd4-b61c-7326db95828a' User entered '04 Dec 2020 15:16:13'	System	04 Dec 2020 22:16:16
	System	04 Dec 2020 22:16:16

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-13T10:49:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '4458422f-04ee-4edd-b4f1-149aad80b16'	System	13 Dec 2020 17:49:32
User entered 'No (N)'	System	13 Dec 2020 17:49:32

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-13T10:49:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '4458422f-04ee-4edd-b4f1-149aaad80b16'	System	13 Dec 2020 17:49:32
User entered 'No (N)'	System	13 Dec 2020 17:49:32

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-13T10:49:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '4458422f-04ee-4edd-b4f1-149aaad80b16'	System	13 Dec 2020 17:49:32
User entered '13 Dec 2020 10:49:27'	System	13 Dec 2020 17:49:32

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-18T12:35:51', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5b45b532-903a-4b90-bab2-b76f66c4df6b' User entered 'Yes (Y)'	System	18 Dec 2020 19:36:34
	System	18 Dec 2020 19:36:34

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-18T12:35:55', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5b45b532-903a-4b90-bab2-b76f66c4df6b' User entered 'No (N)'	System	18 Dec 2020 19:36:34
	System	18 Dec 2020 19:36:34

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-18T12:35:59', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5b45b532-903a-4b90-bab2-b76f66c4df6b' User entered 'No (N)'	System	18 Dec 2020 19:36:34
	System	18 Dec 2020 19:36:34

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-18T12:36:09', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5b45b532-903a-4b90-bab2-b76f66c4df6b'	System	18 Dec 2020 19:36:34
User entered 'Yes (Y)'	System	18 Dec 2020 19:36:34

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Please 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-18T12:36:17', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5b45b532-903a-4b90-bab2-b76f66c4df6b'	System	18 Dec 2020 19:36:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 19:36:34

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-18T12:36:25', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '5b45b532-903a-4b90-bab2-b76f66c4df6b' User entered '18 Dec 2020 12:36:25'	System	18 Dec 2020 19:36:34
	System	18 Dec 2020 19:36:34

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-26T13:09:50', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '045401da-82d3-4367-adfa-7c8061c92aec' User entered 'No (N)'	System	26 Dec 2020 20:10:06
	System	26 Dec 2020 20:10:06

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-26T13:09:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '045401da-82d3-4367-adfa-7c8061c92aec' User entered 'No (N)'	System	26 Dec 2020 20:10:06
	System	26 Dec 2020 20:10:06

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2020-12-26T13:10:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '045401da-82d3-4367-adfa-7c8061c92aec' User entered '26 Dec 2020 13:10:00'	System	26 Dec 2020 20:10:06
	System	26 Dec 2020 20:10:06

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-05T13:54:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e9fa5634-442f-4db0-af0e-c81bb8afe98a' User entered 'No (N)'	System	05 Jan 2021 20:54:46
	System	05 Jan 2021 20:54:46

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-05T13:54:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e9fa5634-442f-4db0-af0e-c81bb8afe98a' User entered 'No (N)'	System	05 Jan 2021 20:54:46

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-05T13:54:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e9fa5634-442f-4db0-af0e-c81bb8afe98a' User entered '05 Jan 2021 13:54:44'	System	05 Jan 2021 20:54:46
	System	05 Jan 2021 20:54:46

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-10T23:27:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '4cde3265-7f81-4d10-abe2-344b0a86f2aa' User entered 'No (N)'	System	11 Jan 2021 06:27:33
	System	11 Jan 2021 06:27:33

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-10T23:27:20', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '4cde3265-7f81-4d10-abe2-344b0a86f2aa'	System	11 Jan 2021 06:27:33
User entered 'No (N)'	System	11 Jan 2021 06:27:33

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-10T23:27:27', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '4cde3265-7f81-4d10-abe2-344b0a86f2aa' User entered '10 Jan 2021 23:27:27'	System	11 Jan 2021 06:27:33
	System	11 Jan 2021 06:27:33

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-18T08:36:04', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'f2801a1d-18a0-40f9-bfc0-66f399065c06'	System	18 Jan 2021 15:36:25
User entered 'No (N)'	System	18 Jan 2021 15:36:25

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-18T08:36:13', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'f2801a1d-18a0-40f9-bfc0-66f399065c06'	System	18 Jan 2021 15:36:25
User entered 'No (N)'	System	18 Jan 2021 15:36:25

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-18T08:36:23', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'f2801a1d-18a0-40f9-bfc0-66f399065c06' User entered '18 Jan 2021 08:36:23'	System	18 Jan 2021 15:36:25
	System	18 Jan 2021 15:36:25

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-24T11:27:40', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae0e600d-da19-42e1-bbcd-8a1834e81fbd' User entered 'No (N)'	System	24 Jan 2021 18:27:55
	System	24 Jan 2021 18:27:55

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-24T11:27:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae0e600d-da19-42e1-bbcd-8a1834e81fbd' User entered 'No (N)'	System	24 Jan 2021 18:27:55
	System	24 Jan 2021 18:27:55

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-24T11:27:50', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ae0e600d-da19-42e1-bbcd-8a1834e81fbd' User entered '24 Jan 2021 11:27:50'	System	24 Jan 2021 18:27:55
	System	24 Jan 2021 18:27:55

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-29T09:13:44', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ce59cc81-6c3e-4a9d-a3fa-d33a89d6222b'	System	29 Jan 2021 16:14:07
User entered 'No (N)'	System	29 Jan 2021 16:14:07

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-29T09:13:48', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ce59cc81-6c3e-4a9d-a3fa-d33a89d6222b'	System	29 Jan 2021 16:14:07
User entered 'No (N)'	System	29 Jan 2021 16:14:07

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-01-29T09:14:03', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'ce59cc81-6c3e-4a9d-a3fa-d33a89d6222b' User entered '29 Jan 2021 09:14:03'	System	29 Jan 2021 16:14:07
	System	29 Jan 2021 16:14:07

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-05T08:10:09', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '92951b3a-6ba6-48f9-b22b-9549ee7dcbd7' User entered 'No (N)'	System	05 Feb 2021 15:11:03
	System	05 Feb 2021 15:11:03

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-05T08:10:16', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '92951b3a-6ba6-48f9-b22b-9549ee7dcbd7' User entered 'Yes (Y)'	System	05 Feb 2021 15:11:03
	System	05 Feb 2021 15:11:03

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Please 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-05T08:10:38', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '92951b3a-6ba6-48f9-b22b-9549ee7dcbd7'	System	05 Feb 2021 15:11:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 15:11:03

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-05T08:10:52', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '92951b3a-6ba6-48f9-b22b-9549ee7dcbd7' User entered '05 Feb 2021 08:10:52'	System	05 Feb 2021 15:11:03
	System	05 Feb 2021 15:11:03

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-12T00:39:36', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '9b6bb381-c289-4309-aef2-c250806ea65c' User entered 'No (N)'	System	12 Feb 2021 07:39:50
	System	12 Feb 2021 07:39:50

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-12T00:39:42', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '9b6bb381-c289-4309-aef2-c250806ea65c' User entered 'No (N)'	System	12 Feb 2021 07:39:50
	System	12 Feb 2021 07:39:50

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-12T00:39:47', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '9b6bb381-c289-4309-aef2-c250806ea65c' User entered '12 Feb 2021 00:39:47'	System	12 Feb 2021 07:39:50
	System	12 Feb 2021 07:39:50

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-19T00:32:54', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3bde60e-71a7-4cf2-bceb-a1031d6de985'	System	19 Feb 2021 07:33:05
User entered 'No (N)'	System	19 Feb 2021 07:33:05

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-19T00:32:58', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3bde60e-71a7-4cf2-bceb-a1031d6de985'	System	19 Feb 2021 07:33:05
User entered 'No (N)'	System	19 Feb 2021 07:33:05

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-19T00:33:02', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e3bde60e-71a7-4cf2-bceb-a1031d6de985' User entered '19 Feb 2021 00:33:02'	System	19 Feb 2021 07:33:05
	System	19 Feb 2021 07:33:05

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-26T00:01:29-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1a29211a-1d4e-405b-a0f5-808bb384c496'	System	26 Feb 2021 09:28:59
User entered 'No (N)'	System	26 Feb 2021 09:28:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-26T00:01:33-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1a29211a-1d4e-405b-a0f5-808bb384c496' User entered 'No (N)'	System	26 Feb 2021 09:28:59
	System	26 Feb 2021 09:28:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-26T00:01:43-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1a29211a-1d4e-405b-a0f5-808bb384c496'	System	26 Feb 2021 09:28:59
User entered '26 Feb 2021 07:01:43'	System	26 Feb 2021 09:28:59

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-05T01:21:22-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e7886e67-ca8a-44d1-9a56-6e2b3418b114'	System	05 Mar 2021 08:21:35
User entered 'No (N)'	System	05 Mar 2021 08:21:35

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-05T01:21:25-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e7886e67-ca8a-44d1-9a56-6e2b3418b114'	System	05 Mar 2021 08:21:35
User entered 'No (N)'	System	05 Mar 2021 08:21:35

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-05T01:21:30-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'e7886e67-ca8a-44d1-9a56-6e2b3418b114'	System	05 Mar 2021 08:21:35
User entered '05 Mar 2021 01:21:30'	System	05 Mar 2021 08:21:35

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-12T10:28:31-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc582f7c-8e59-4816-93e4-95c39ac78a56'	System	12 Mar 2021 17:28:43
User entered 'No (N)'	System	12 Mar 2021 17:28:43

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-12T10:28:36-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc582f7c-8e59-4816-93e4-95c39ac78a56'	System	12 Mar 2021 17:28:43
User entered 'No (N)'	System	12 Mar 2021 17:28:43

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-12T10:28:41-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'cc582f7c-8e59-4816-93e4-95c39ac78a56'	System	12 Mar 2021 17:28:43
User entered '12 Mar 2021 10:28:41'	System	12 Mar 2021 17:28:43

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-19T00:27:03-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '079364d4-fff1-4e43-9bb1-0d6a3807127f' User entered 'No (N)'	System	19 Mar 2021 07:27:13

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-19T00:27:07-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '079364d4-fff1-4e43-9bb1-0d6a3807127f' User entered 'No (N)'	System	19 Mar 2021 07:27:13
	System	19 Mar 2021 07:27:13

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-19T00:27:10-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '079364d4-fff1-4e43-9bb1-0d6a3807127f' User entered '19 Mar 2021 00:27:10'	System	19 Mar 2021 07:27:13
	System	19 Mar 2021 07:27:13

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-26T07:28:35-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'bbba8492-a32c-4fdc-968c-2a9410cd486f'	System	26 Mar 2021 14:28:55
User entered 'No (N)'	System	26 Mar 2021 14:28:55

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-26T07:28:45-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'bbba8492-a32c-4fdc-968c-2a9410cd486f'	System	26 Mar 2021 14:28:55
User entered 'No (N)'	System	26 Mar 2021 14:28:55

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-03-26T07:28:49-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'bbba8492-a32c-4fdc-968c-2a9410cd486f' User entered '26 Mar 2021 07:28:49'	System	26 Mar 2021 14:28:55
	System	26 Mar 2021 14:28:55

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-02T09:00:08-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '335a2c5f-0d70-40e9-ba40-0e56b0a19e10'	System	02 Apr 2021 16:00:26
User entered 'No (N)'	System	02 Apr 2021 16:00:26

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-02T09:00:12-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '335a2c5f-0d70-40e9-ba40-0e56b0a19e10'	System	02 Apr 2021 16:00:26
User entered 'No (N)'	System	02 Apr 2021 16:00:26

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-02T09:00:18-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '335a2c5f-0d70-40e9-ba40-0e56b0a19e10'	System	02 Apr 2021 16:00:26
User entered '02 Apr 2021 09:00:18'	System	02 Apr 2021 16:00:26

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-09T00:14:19-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'fef93bc7-8a18-4d58-90b2-b748da620e54' User entered 'No (N)'	System	09 Apr 2021 07:14:45
	System	09 Apr 2021 07:14:45

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-09T00:14:21-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'fef93bc7-8a18-4d58-90b2-b748da620e54'	System	09 Apr 2021 07:14:45
User entered 'No (N)'	System	09 Apr 2021 07:14:45

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-09T00:14:41-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'fef93bc7-8a18-4d58-90b2-b748da620e54'	System	09 Apr 2021 07:14:45
User entered '09 Apr 2021 00:14:41'	System	09 Apr 2021 07:14:45

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-16T13:19:27-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c27ed874-5c1c-4c21-ae33-be22b7b95a9a'	System	16 Apr 2021 20:20:15
User entered 'Yes (Y)'	System	16 Apr 2021 20:20:15

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-16T13:19:33-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c27ed874-5c1c-4c21-ae33-be22b7b95a9a' User entered 'No (N)'	System	16 Apr 2021 20:20:15
	System	16 Apr 2021 20:20:15

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-16T13:19:40-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c27ed874-5c1c-4c21-ae33-be22b7b95a9a' User entered 'No (N)'	System	16 Apr 2021 20:20:15
	System	16 Apr 2021 20:20:15

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-16T13:19:50-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c27ed874-5c1c-4c21-ae33-be22b7b95a9a'	System	16 Apr 2021 20:20:15
User entered 'Yes (Y)'	System	16 Apr 2021 20:20:15

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Please 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-16T13:19:55-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c27ed874-5c1c-4c21-ae33-be22b7b95a9a'	System	16 Apr 2021 20:20:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Apr 2021 20:20:15

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-16T13:20:00-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: 'c27ed874-5c1c-4c21-ae33-be22b7b95a9a' User entered '16 Apr 2021 13:20:00'	System	16 Apr 2021 20:20:15
	System	16 Apr 2021 20:20:15

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-23T00:35:18-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1bdad6d3-34fc-4f90-b7db-21a054b31866'	System	23 Apr 2021 07:35:37
User entered 'No (N)'	System	23 Apr 2021 07:35:37

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-23T00:35:29-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1bdad6d3-34fc-4f90-b7db-21a054b31866'	System	23 Apr 2021 07:35:37
User entered 'No (N)'	System	23 Apr 2021 07:35:37

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-23T00:35:34-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1bdad6d3-34fc-4f90-b7db-21a054b31866'	System	23 Apr 2021 07:35:37
User entered '23 Apr 2021 00:35:34'	System	23 Apr 2021 07:35:37

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-30T08:44:30-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '843be637-74d5-4565-a461-793170aecae8' User entered 'No (N)'	System	30 Apr 2021 15:44:51
	System	30 Apr 2021 15:44:51

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

Have you been exposed to someone with 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 (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-30T08:44:35-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '843be637-74d5-4565-a461-793170aecae8'	System	30 Apr 2021 15:44:51
User entered 'No (N)'	System	30 Apr 2021 15:44:51

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-04-30T08:44:48-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '843be637-74d5-4565-a461-793170aecae8'	System	30 Apr 2021 15:44:51
User entered '30 Apr 2021 08:44:48'	System	30 Apr 2021 15:44:51

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:35:19

US3792016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:35:19
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:35:19

US3792016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-27T23:58:45-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1c616320-5836-453a-8616-85c6e7f7ca00'	System	28 Feb 2021 06:58:57
User entered 'No (N)'	System	28 Feb 2021 06:58:57

US3792016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9406203A-E4C4-41BD-BEAB-033E6F7BB52A)', Time: '2021-02-27T23:58:54-07:00', User OID: 'PatientReportedOutcome (US3792016)', ODM File OID: '1c616320-5836-453a-8616-85c6e7f7ca00' User entered '27 Feb 2021 23:58:54'	System	28 Feb 2021 06:58:57
	System	28 Feb 2021 06:58:57

US3792016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	05 Nov 2020 18:56:07

US3792016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '5 Nov 2020'	Ann Marie Milliken	05 Nov 2020 18:56:07

US3792016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	05 Nov 2020 18:56:07

US3792016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	05 Nov 2020 18:56:07

US3792016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	05 Nov 2020 18:56:12

US3792016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:07:46
User entered 'I'	System	05 Nov 2020 18:56:12

US3792016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	08 Dec 2020 18:48:08

US3792016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '8 Dec 2020'	(b) (4) Ann Marie Milliken (b) (4)	08 Dec 2020 18:48:08

US3792016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	08 Dec 2020 18:48:08

US3792016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	08 Dec 2020 18:48:08

US3792016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	08 Dec 2020 18:48:14

US3792016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'I'	System	08 Dec 2020 18:48:14

US3792016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Ann Marie Milliken	08 Jan 2021 18:07:06

US3792016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '7 Jan 2021'	Ann Marie Milliken	08 Jan 2021 18:07:06

US3792016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	08 Jan 2021 18:07:06

US3792016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	08 Jan 2021 18:07:06

US3792016

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	08 Jan 2021 18:07:11

US3792016

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'I'	System	08 Jan 2021 18:07:11

US3792016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	30 Mar 2021 16:46:48

US3792016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '8 Feb 2021'	Ann Marie Milliken	30 Mar 2021 16:46:48

US3792016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	30 Mar 2021 16:46:48

US3792016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	30 Mar 2021 16:46:48

US3792016

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Mar 2021 17:44:51

US3792016

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'I'	System	09 Mar 2021 17:44:51

US3792016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Mar 2021 18:23:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 18:23:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 18:23:35
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 18:23:07
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 18:23:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:23:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:23:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'VISIT4'	System	09 Mar 2021 18:23:35
User entered empty.	System	09 Mar 2021 18:23:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Yes (Y)'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '8 Mar 2021'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '10:49'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered '8 Mar 2021 10:49'	System	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '98.7' F	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '94'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'bpm'	System	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '16'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'breaths/min'	System	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '92'	Norma Frederick (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'mmHg'	System	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 11:52:56
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per sub Investigator ' (Site from System).	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:44:01
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Mar 2021 19:43:50
User entered '58'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'mmHg'	System	30 Mar 2021 19:43:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09

US3792016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09

US3792016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:23:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:23:50

US3792016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:29:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:29:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '11:05'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:29:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered '8 Mar 2021 11:05'	System	09 Mar 2021 18:29:07

US3792016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:29:28

US3792016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:16:09
User entered 'I'	System	09 Mar 2021 18:29:28

US3792016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:46
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:49:38
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 20:26:12

US3792016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:46
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:49:38
User entered '5 Apr 2021'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 20:26:12

US3792016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:46
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:49:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 20:26:12

US3792016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:46
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:49:38
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 20:26:12

US3792016

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:46
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:49:38
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 20:26:22

US3792016

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:58:46
User entered 'I'	System	07 Apr 2021 20:26:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:37:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 22:55:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 22:55:29
User entered '13:30' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 22:55:29
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 16:37:54
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:37:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 13:30'	System	22 Apr 2021 22:55:29
User entered empty.	System	22 Apr 2021 16:37:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:37:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:37:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:20:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:25:49

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:21

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:26:54

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:22

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:27:45

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:28:33

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '18 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:29:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:26

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:32:07

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:48:55

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:33:57

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 16:41:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 16:41:31
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 16:41:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 16:40:42
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 17:38:33
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 16:42:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 17:38:33
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Apr 2021 16:43:17
User entered 'Deer Valley Medical Center' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 16:43:17
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Apr 2021 16:42:00
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 17:38:33
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Apr 2021 16:43:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Apr 2021 16:43:17
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Apr 2021 16:42:00
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:40:42

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 16:41:31

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:48:55

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:41:04

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:43:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 22:56:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 22:56:56
User entered '13:30' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 22:56:56
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 16:43:05
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:43:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 13:30'	System	22 Apr 2021 22:56:56
User entered empty.	System	22 Apr 2021 16:43:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:43:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:43:05

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Nasal Swab (Nasal Swab)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Honor Health Deer Valley'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:46:15

US3792016

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:48:55

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 16:46:15

US3792016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:47:03

US3792016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:47:03

US3792016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:47:03

US3792016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	22 Apr 2021 16:47:03

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13:05'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Apr 2021 13:05'	System	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Height (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 22:56:14
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 16:48:38
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Apr 2021 16:48:24
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:48:24
DataPoint set to visible.	System	22 Apr 2021 16:47:03

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Weight (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 22:56:16
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 16:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Apr 2021 16:48:24
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 16:48:24
DataPoint set to visible.	System	22 Apr 2021 16:47:03

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '68'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '111'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '62'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 16:48:24

US3792016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:51

US3792016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:48:51

US3792016

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:48:55

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:49:02

US3792016

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:48:55

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:49:02

US3792016

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:33

US3792016

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '7 Jan 2021'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:33

US3792016

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Clinic (Clinic)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:33

US3792016

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 00:04:33

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '7 Jan 2021'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:00

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:00

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '7 Jan 2021'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'mRNA-1273 (mRNA-1273)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 07:08:43
User entered 'mRNA-1273 (mRNA-1273)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58
	(b) (4)	

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 07:08:43
User entered 'mRNA-1273 (mRNA-1273)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58
	(b) (4)	

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:04:58

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User entered empty.	System	08 Jan 2021 00:04:58

US3792016

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User entered empty.	System	08 Jan 2021 00:04:58

US3792016

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:05:21

US3792016

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '7 Jan 2021'	Scarlett Hammett (b) (4)	08 Jan 2021 00:05:21

US3792016

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '12:53'	Scarlett Hammett (b) (4)	08 Jan 2021 00:05:21

US3792016

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User entered '7 Jan 2021 12:53'	System	08 Jan 2021 00:05:21

US3792016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:05:37

US3792016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '7 Jan 2021'	Scarlett Hammett (b) (4)	08 Jan 2021 00:05:37

US3792016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered '12:58'	Scarlett Hammett (b) (4)	08 Jan 2021 00:05:37

US3792016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:06
User entered '7 Jan 2021 12:58'	System	08 Jan 2021 00:05:37

US3792016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:48:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:03
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:06:25

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:40:01
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	Norma Frederick (b) (4)	13 Mar 2021 17:25:43
' answered with 'according to crc note, "not a covid-19 symptom" therefore no illness visit was conducted ' (Site from DM).	(b) (4)	
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	03 Feb 2021 19:23:42
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:09:46
Data point term sent to Coder	System	08 Jan 2021 00:08:41
User entered 'SINUS INFECTION'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Yes (Y)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'No (N)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'No (N)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '17 Dec 2020'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User entered empty.	System	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'No (N)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '25 Dec 2020'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User entered empty.	System	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00
	(b) (4)	

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'No (N)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Not Related (NOT RELATED)'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00
	(b) (4)	

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'I'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '0'	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) Scarlett Hammett (b) (4)	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User entered '0'	System	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51
User entered '1'	System	08 Jan 2021 00:08:00

US3792016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:14:51

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:58:48
User entered 'USA-US057-2021-mRNA-1273-P301000003'	System	20 Apr 2021 16:44:49
User entered 'New'	(b) (4), (b) (6)	20 Apr 2021 16:44:49

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis, LLT: Pancreatitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Apr 2021 20:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 20:37:40
Data point term sent to Coder	System	19 Apr 2021 20:36:48
User entered 'Pancreatitis'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
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).	(b) (4)	19 Apr 2021 20:37:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:37:16
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	19 Apr 2021 20:36:45
User entered '23:30'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:37:16
User entered '10 Apr 2021 23:30'	System	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:16:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:43:53
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:40:34
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:04:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	28 Apr 2021 16:44:17
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Apr 2021 16:44:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Apr 2021 16:42:58
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Apr 2021 16:42:58
User entered '19 Apr 2021' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:42:58
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Apr 2021 16:40:34
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admission date entered, ICU question answered, Patient is still hospitalized ' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 20:39:50
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Apr 2021 20:36:45
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '19 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 16:51:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:46:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 20:46:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:46:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:36:45
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:46:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 20:46:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:46:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:36:45
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:16:50
Query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:44:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:42:58
User opened query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:03:51
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

None

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Norma Frederick (b) (4)	28 Apr 2021 16:45:11
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 20:39:00
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:39:00
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 20:36:45
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:16:56
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:46:29
User entered '1' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:45:11
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:04:32
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:17:15
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:47:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:44:17
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:04:40
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:40:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 20:40:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:40:13
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:36:45
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 11:23:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'records sent ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 18:52:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 18:17:37
User closed query 'PV Query: Please confirm date of MRI and CT. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 18:17:26
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Covid-19 test was done on 4/13/2021 POC Covid-19 Molecular, Abbott ID NOW Nasal Swab' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 17:01:47
Query 'PV Query: Please confirm date of MRI and CT. If unknown, please indicate so.' answered with 'updated ' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	28 Apr 2021 16:59:12

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT BEGAN EXPERIENCING ABDOMINAL PAIN ON 10APR2021 AT ~ 2230. ON 13APR2021 PT CALLED PCP WHO INSTRUCTED TO CALL 911. PT TRANSPORTED TO HOSPITAL ON 13APR2021. MRCP unremarkable, mild hepatic steatosis, mild edema around pancreatic tail CT REVEALED PANCREATITIS. MRI DATE: 4/16/201 CT ABDOMEN/PELVIS ON 4/13/21 revealed inflammation of pancreas' reason for change: Data Entry Error	Norma Frederick (b) (4)	28 Apr 2021 16:58:37
User entered 'PATIENT BEGAN EXPERIENCING ABDOMINAL PAIN ON 10APR2021 AT ~ 2230. ON 13APR2021 PT CALLED PCP WHO INSTRUCTED TO CALL 911. PT TRANSPORTED TO HOSPITAL ON 13APR2021. MRI/CT REVEALED PANCREATITIS. MRI DATE: 4/16/201 CT ABDOMEN/PELVIS ON 4/13/21' reason for change: Data Entry Error	Norma Frederick (b) (4)	28 Apr 2021 16:50:14
User entered 'PATIENT BEGAN EXPERIENCING ABDOMINAL PAIN ON 10APR2021 AT ~ 2230. ON 13APR2021 PT CALLED PCP WHO INSTRUCTED TO CALL 911. PT TRANSPORTED TO HOSPITAL ON 13APR2021. MRI/CT REVEALED PANCREATITIS. MRI date: 4/16/201 CT abdomen/pelvis on 4/13/21' reason for change: Data Entry Error	Norma Frederick (b) (4)	28 Apr 2021 16:49:58
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:04:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:04:07

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm date of MRI and CT. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 12:04:01
User entered 'Patient began experiencing abdominal pain on 10APR2021 at ~ 2230. On 13APR2021 pt called PCP who instructed to call 911. Pt transported to Hospital on 13APR2021. MRI/CT revealed Pancreatitis.'	(b) (4), (b) (6)	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:36:45

US3792016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 20:36:45

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:48:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:03
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:08:27

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TAPENTADOL HYDROCHLORIDE, PRODUCTSYNONYM: NUCYNTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 15:55:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:55:40
Data point term sent to Coder	System	08 Jan 2021 00:10:42
User entered 'NUCUNTA'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:09:51

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'FIBROMYALGIA'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '100'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'twice daily (BID)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '20 Jan 2017'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:09:51
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 00:09:51

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:09:51

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:09:51

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 00:14:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:14:45
Data point term sent to Coder	System	08 Jan 2021 00:13:42
User entered 'METHOCARBAMOL'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:13:22

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'FIBROMYALGIA'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '750'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'three times daily (TID)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '20 Jan 2016'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:13:22
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Jan 2021 00:13:22

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:13:22

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:13:22

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 00:15:58
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 Jan 2021 00:15:58
Data point term sent to Coder	System	08 Jan 2021 00:15:43
User entered 'OXYCODONE'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:14:48

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'FIBROMYALGIA'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '5'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '20 Jan 2016'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:14:48
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:14:48

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:14:48

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:14:48

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 00:18:52
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 Jan 2021 00:18:52
Data point term sent to Coder	System	08 Jan 2021 00:17:44
User entered 'PROMETHAZINE'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:17:41

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:02:26
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'PROMETHAZINE IS USED TO PREVENT NAUSEA SECONDARY TO MIGRAINE HEADACHE' (Site from DM).	(b) (4) Scarlett Hammett (b) (4)	17 Feb 2021 00:31:17
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 04:05:00
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'INTERMITTENT NAUSEA'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '25'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'as needed (PRN)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'UN Jan 2000'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:17:41
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:17:41

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:17:41

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:17:41

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 00:20:49
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 Jan 2021 00:20:49
Data point term sent to Coder	System	08 Jan 2021 00:19:44
User entered 'CELECOXIB'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:19:28

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'DEGENERATIVE DISC DISEASE'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '200'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'UN Jan 2014'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:19:28
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:19:28

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:19:28

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:19:28

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 00:28:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:28:50
Data point term sent to Coder	System	08 Jan 2021 00:27:45
User entered 'ACETAMINOPHEN'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:27:29

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'DEGENERATIVE DISC DISEASE'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '500'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'as needed (PRN)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'UN Jan 2012'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:27:29
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:27:29

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:27:29

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:27:29

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 15:13:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:13:40
Data point term sent to Coder	System	08 Jan 2021 00:30:50
User entered 'GUIFENISEN'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:30:32

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'FIBROMYALGIA'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '2000'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'twice daily (BID)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'UN UNK 2000'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:30:32
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 00:30:32

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:30:32

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:30:32

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 00:34:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:34:46
Data point term sent to Coder	System	08 Jan 2021 00:33:51
User entered 'OMEPRAZOLE'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:32:55

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'ACID REFLUX'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '20'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'UN UNK 2008'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:32:55
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:32:55

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:32:55

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:32:55

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 15:44:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 15:44:41
Data point term sent to Coder	System	08 Jan 2021 00:34:51
User entered 'MAGNESIUM OXIDE'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:34:18

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'FIBROMYALGIA'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '400'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'twice daily (BID)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'UN UNK 2010'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:34:18
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 00:34:18

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:34:18

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:34:18

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN MESILATE, PRODUCTSYNONYM: CARDURA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 00:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:37:46
Data point term sent to Coder	System	08 Jan 2021 00:36:52
User entered 'CARDURA'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:35:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'HYPERTENSION'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:11:43
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' answered with 'CORRECTED' (Site from DM).	Scarlett Hammett (b) (4) (b) (4)	17 Feb 2021 00:32:11
User entered '4' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	17 Feb 2021 00:31:59
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 07:37:41
User entered '400'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:35:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '01 Jul 2020'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:35:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:35:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:35:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:35:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 00:38:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 00:38:46
Data point term sent to Coder	System	08 Jan 2021 00:37:52
User entered 'HYDROCHLOROTHIAZIDE'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:37:13

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'HYPERTENSION'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '12.5'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '01 Jul 2020'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:37:13
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:37:13

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:37:13

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:37:13

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
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.	(b) (4) Coder Import (b) (4)	08 Jan 2021 00:40:51
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 Jan 2021 00:40:51
Data point term sent to Coder	System	08 Jan 2021 00:39:55
User entered 'INFLUENZA VACCINATION'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:39:05

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'INFLUENZA PROPHYLAXIS'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '1'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Other (OTHER)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'INJECTION'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'once (ONCE)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '10 Oct 2020'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '10 Oct 2020'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:39:05
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:39:05

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:39:05

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:39:05

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Jan 2021 14:22:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:22:40
Data point term sent to Coder	System	08 Jan 2021 00:42:01
User entered 'AMOXICILLIN 500 MG - CLAVULANIC ACID 125'	Scarlett Hammett (b) (4) (b) (4)	08 Jan 2021 00:40:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'SINUS INFECTION'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '1'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'tablet (TABLET)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'twice daily (BID)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '17 Dec 2020'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered '24 Dec 2020'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	08 Jan 2021 00:40:58
	(b) (4)	

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 00:40:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:40:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 00:40:58

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:28:52
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 Apr 2021 16:28:52
Data point term sent to Coder	System	23 Apr 2021 16:06:20
User entered 'Pantoprazole'	(b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Pancreatitis'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '40'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:05:59

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DIGESTIVES, INCL. ENZYMES, ATC: DIGESTIVES, INCL. ENZYMES, ATC: ENZYME PREPARATIONS, PRODUCT: PANCRELIPASE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:11:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:11:10
Data point term sent to Coder	System	23 Apr 2021 16:10:25
User entered 'Pancrelipase'	(b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Pancreatitis'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '60000'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:09:30

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:11:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:11:10
Data point term sent to Coder	System	23 Apr 2021 16:10:25
User entered 'Zofran'	(b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Pancreatitis'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '4'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 16:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:10:24
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:10:24

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:48:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:03
User closed query 'Per ETRTR: According to SAE page "Pancreatitis", Narrative states a CT was performed to confirm diagnosis, but the same is missing in this folder. Please add Concomitant Procedure details for SAE as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 20:37:00
Query 'Per ETRTR: According to SAE page "Pancreatitis", Narrative states a CT was performed to confirm diagnosis, but the same is missing in this folder. Please add Concomitant Procedure details for SAE as applicable, thanks.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 22:51:41
User opened query 'Per ETRTR: According to SAE page "Pancreatitis", Narrative states a CT was performed to confirm diagnosis, but the same is missing in this folder. Please add Concomitant Procedure details for SAE as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:49:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:55:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 18:55:07
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:54:22
User entered 'No (N)'	(b) (4) Scarlett Hammett (b) (4)	13 Feb 2021 00:53:09

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:08
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:55:52

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:08
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Right Cataract removal'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:55:52

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:08
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:55:52

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:08
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:55:52

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:56:45

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Left Cataract removal'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:56:45

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:56:45

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:55

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:55:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:56:45

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:49:26

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'CT Abdomen and Pelvis with Contrast'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:49:26

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:51:54
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	22 Apr 2021 22:49:26

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 22:49:26

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:51:27

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Upper Endoscopy'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:51:27

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:51:27

US3792016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:51:27

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'USA-US057-2021-MRNA-1273-P301000003'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Abram'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Burgher'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '3900 East Camelback Road'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Phoenix'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 11:24:58
User entered empty.	System	29 Apr 2021 11:24:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User entered 'Arizona'	Norma Frederick (b) (4)	28 Apr 2021 18:51:32
	(b) (4)	

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '85018'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'US'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 11:24:58
User entered '3'	System	28 Apr 2021 18:18:34
User entered '2'	System	22 Apr 2021 21:59:08
User entered '1'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'USA-US057-2021-MRNA-1273-P301000003'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Abram'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Burgher'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '3900 East Camelback Road'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Phoenix'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 11:24:58
User entered empty.	System	29 Apr 2021 11:24:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User entered 'Arizona'	Norma Frederick (b) (4)	28 Apr 2021 18:51:32
	(b) (4)	

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '85018'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'US'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 11:24:58
User entered '3'	System	28 Apr 2021 18:18:34
User entered '2'	System	22 Apr 2021 21:59:08
User entered '1'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '20/Apr/2021 12:46'	(b) (4) System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'USA-US057-2021-MRNA-1273-P301000003'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Abram'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Burgher'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '3900 East Camelback Road'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Phoenix'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 11:24:58
User entered empty.	System	29 Apr 2021 11:24:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User entered 'Arizona'	Norma Frederick (b) (4)	28 Apr 2021 18:51:32
	(b) (4)	

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '85018'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'US'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 11:24:58
User entered '3'	System	28 Apr 2021 18:18:34
User entered '2'	System	22 Apr 2021 21:59:08
User entered '1'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered '22/Apr/2021 17:59'	(b) (4) System	22 Apr 2021 21:59:08

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:59:08

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'USA-US057-2021-MRNA-1273-P301000003'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Abram'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Burgher'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '3900 East Camelback Road'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Phoenix'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 11:24:58
User entered empty.	System	29 Apr 2021 11:24:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User entered 'Arizona'	Norma Frederick (b) (4)	28 Apr 2021 18:51:32
	(b) (4)	

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '85018'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'US'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 11:24:58
User entered '3'	System	28 Apr 2021 18:18:34
User entered '2'	System	22 Apr 2021 21:59:08
User entered '1'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:48:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '28/Apr/2021 14:18'	(b) (4) System	28 Apr 2021 18:18:34

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:48:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User entered 'I'	(b) (4), (b) (6)	28 Apr 2021 18:18:34

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'USA-US057-2021-MRNA-1273-P301000003'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Yes (Y)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'No (N)'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Abram'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Burgher'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '3900 East Camelback Road'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'Phoenix'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 11:24:58
User entered empty.	System	29 Apr 2021 11:24:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 11:24:36
User entered 'Arizona'	Norma Frederick (b) (4)	28 Apr 2021 18:51:32
	(b) (4)	

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered '85018'	System	20 Apr 2021 16:44:49

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:46:47
User entered 'US'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	29 Apr 2021 11:24:58
User entered '3'	System	28 Apr 2021 18:18:34
User entered '2'	System	22 Apr 2021 21:59:08
User entered '1'	System	20 Apr 2021 16:46:29

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:48:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered '29/Apr/2021 07:24'	(b) (4) System	29 Apr 2021 11:24:58

US3792016

Folder: SAE USA-US057-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:48:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	29 Apr 2021 15:12:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 11:24:58