

US3752184 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3752184

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:44:14

Generated On: 10 Jun 2021 09:45:50

[Participant ID](#)

US3752184

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

US3752184

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
Sex	Female <input type="radio"/> Male <input checked="" 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) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 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) 12 Feb 2021 18:44:42

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:44:43

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Condition	NEUROPATHY (UNKNOWN TYPE & UNKNOWN LOCATION)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Condition	MELANOMA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Condition	PROSTATE SURGERY FOR PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:40
Height (<i>xxx.x</i>)	66.5 in
Weight (<i>xxx.x</i>)	173.2 lb
BMI (<i>xxx.x</i>)	27.59399 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) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:44:43

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

OUTDOOR SERVICE PROVIDER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:44:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187403

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) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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)	20 AUG 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:40
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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)	20 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 14:30 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 14:30

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	14:00 (24 HR)
Collection date and time (derived)	20 AUG 2020 14:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:48	20 AUG 2020 13:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 14:59

PC Open Date & Time

20 AUG 2020 14:50

PC Close Date & Time

20 AUG 2020 17:20

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	20 AUG 2020 20:13
PC Open Date & Time	20 AUG 2020 18:15
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

98.3 °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

21 AUG 2020 20:49

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

97.2 °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

22 AUG 2020 18:57

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

23 AUG 2020 17:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

24 AUG 2020 19:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

97.6 °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

25 AUG 2020 19:11

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

26 AUG 2020 20:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

20 AUG 2020 15:00

PC Open Date & Time

20 AUG 2020 14:50

PC Close Date & Time

20 AUG 2020 17:20

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

20 AUG 2020 20:13

PC Open Date & Time

20 AUG 2020 18:15

PC Close Date & Time

21 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

21 AUG 2020 20:49

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

22 AUG 2020 18:57

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

23 AUG 2020 17:53

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

24 AUG 2020 19:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

25 AUG 2020 19:11

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

26 AUG 2020 20:31

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 14:59
PC Open Date & Time	20 AUG 2020 14:50
PC Close Date & Time	20 AUG 2020 17:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:14
PC Open Date & Time	20 AUG 2020 18:15
PC Close Date & Time	21 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

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 ☒

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:50
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

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 ☒

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:57
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

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 ☒

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EAB) (1725)

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 17:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

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 ☒

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:00
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

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 ☒

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:12
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

57 of 2362

EAB) (1725)

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:31
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3752184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:54
Temperature (xxx.x)	98.1 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)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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)	21 SEP 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:40
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3752184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:22

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

US3752184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	21 SEP 2020 10:55

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:52	21 SEP 2020 10:52
Nasopharyngeal Swab 2	No		

US3752184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °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

21 SEP 2020 11:43

PC Open Date & Time

21 SEP 2020 11:42

PC Close Date & Time

21 SEP 2020 14:12

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.0 °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	21 SEP 2020 19:01
PC Open Date & Time	21 SEP 2020 15:07
PC Close Date & Time	22 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 18:37

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

24 SEP 2020 19:57

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:40

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

21 SEP 2020 11:44

PC Open Date & Time

21 SEP 2020 11:42

PC Close Date & Time

21 SEP 2020 14:12

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

21 SEP 2020 19:02

PC Open Date & Time

21 SEP 2020 15:07

PC Close Date & Time

22 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

23 SEP 2020 18:37

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

24 SEP 2020 19:57

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

25 SEP 2020 18:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

27 SEP 2020 20:40

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 11:44
PC Open Date & Time	21 SEP 2020 11:42
PC Close Date & Time	21 SEP 2020 14:12

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 19:02
PC Open Date & Time	21 SEP 2020 15:07
PC Close Date & Time	22 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

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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US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

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EAB) (1725)

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:37
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

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 ☒

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 19:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

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)

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US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:27
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

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 ☒

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:40
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3752184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:25
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3752184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

11:34 (24 HR)

Collection date and time (derived)

21 OCT 2020 11:34

US3752184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:43

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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°F/38°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"/>

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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°F/38°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"/>

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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°F/38°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"/>

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

09 DEC 2020 10:13:34

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 117

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

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

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

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

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

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

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

13 JAN 2021 21:29:07

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

20 JAN 2021 07:09:15

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

10 FEB 2021 19:37:28

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 02:45:04

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

23 FEB 2021 17:09:09

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 18:18:26

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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	06 MAR 2021 16:13:06
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

13 MAR 2021 21:37:54

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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="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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	28 JUL 2021 23:59
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US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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="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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 432

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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="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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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="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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 <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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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="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"/>

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3752184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:45:50

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 18:18:37

US3752184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 20:26:41

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:17:35

Generated On: 10 Jun 2021 09:45:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 12:40
Temperature (xxx.x)	98.4 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)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 20:26:41

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3752184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 20:26:41

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	12:54 (24 HR)
Collection date and time (derived)	17 MAR 2021 12:54

US3752184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 20:26:41

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 21 Apr 2021 00:13:26

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 21 Apr 2021 00:13:26

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752184

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:45:50

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752184

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

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

Visit date (dd MMM yyyy)	25 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
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US3752184

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:22:40

Generated On: 10 Jun 2021 09:45:50

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3752184

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Height	168.9 cm
Weight	79.9 kg
BMI (xxx.x)	28.00835

US3752184

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Height	168.9 cm
Weight	79.9 kg
BMI (xxx.x)	28.00835
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)	25 JAN 2021
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 11:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3752184

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Height	168.9 cm
Weight	79.9 kg
BMI (xxx.x)	28.00835
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)	25 JAN 2021
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 12:48
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3752184

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3752184

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 JAN 2021

What was the treatment time? (00:00-23:59) 12:18 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 12:18

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

US3752184

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

12:02 (24 HR)

Collection date and time (derived)

25 JAN 2021 12:02

US3752184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00 - 23:59)

12:00

Collection Date and Time (derived)

25 JAN 2021 12:00

US3752184

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:44:42

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3752184

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

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)	26 FEB 2021
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 10:50
Temperature (xxx.x)	97.9 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)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

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)	26 FEB 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:50
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3752184

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3752184

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 11:20

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

US3752184

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:30:00

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 16:19:08

Generated On: 10 Jun 2021 09:45:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 16:19:08

Generated On: 10 Jun 2021 09:45:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752184

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 14:04:59

Generated On: 10 Jun 2021 09:45:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	OLD57

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 14:04:59

Generated On: 10 Jun 2021 09:45:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 APR 2021
Time of assessment (<i>00:00-23:59</i>)	12:25 (24 HR)
Vital Signs Date and Time (derived)	09 APR 2021 12:25
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752184

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 14:04:59

Generated On: 10 Jun 2021 09:45:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 APR 2021

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

US3752184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Apr 2021 14:04:59

Generated On: 10 Jun 2021 09:45:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 APR 2021
Collection time (00:00-23:59)	12:34 (24 HR)
Collection date and time (derived)	09 APR 2021 12:34

US3752184

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 06 Mar 2021 00:29:59

Generated On: 10 Jun 2021 09:45:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

AEID

Adverse event

ESSENTIAL
THROMBOCYTHEMIA WITH
JAK2 MUTATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 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)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

AEID	USA-US113-2021-MRNA-1273-P30 1000007
Adverse event	ACUTE DIVERTICULITIS
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)	31 MAR 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)	10 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)	31 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	2 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

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	True
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	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

SUBJECT ADMITTED TO
HOSPITAL FOR PAIN CONTROL
AND IV ANTIBIOTICS. CT OF
ABDOMEN SHOWS
UNCOMPLICATED
DIVERTICULITIS. DISCHARGED
HOME ON ORAL ANTIBIOTICS
X7 DAYS, SEE CONCOMITANT
MEDICATIONS.

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

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

AEID	
Adverse event	DEGENERATIVE DISC AND JOINT DISEASE L4-S1
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 22:29:28

Generated On: 10 Jun 2021 09:45:50

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:44:14

Generated On: 10 Jun 2021 09:45:50

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

Yes ☒

No ☐

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

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 01:07:16

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Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 60

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) 13 Apr 2021 01:07:16

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	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 2015	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication TRELEGY

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 100/62.5/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 01:07:16

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Name of Medication SEASONAL INFLUENZA
VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF SEASONAL
INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 01:07:16

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	Intraocular	<input type="radio"/>
	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)	29 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)		29 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication PNEUMONIA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PNEUMONIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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)	29 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)		29 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 01:07:16

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Name of Medication BABY ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication THROMBOSIS PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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)	25 FEB 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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

Q2H PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 checked="" 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)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

Dose per administration 8

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

Q2H PRN

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) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 checked="" 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)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication LEVAFLOXACIN IN D5W

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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 (9)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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

Q8H

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication IOHEXOL 350MG IODINE/ML

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	Intramuscular	<input 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 checked="" 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)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 31 MAR 2021		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication 0.9% NACL

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 31 MAR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication 0.9% NACL

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

Dose per administration 80

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

QHOURL

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication ONDANSETRON HCL

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	Intramuscular	<input 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 checked="" 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)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	31 MAR 2021	
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"/>	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication UMECLIDINIUM [INCRUSE
ELLIPTA]

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 62.5

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 ☐

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) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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)	3 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	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)	2 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

Name of Medication ALBUTEROL SULFATE 90
MCG/ACTUATION

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify Q4H PRN

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 (18)

Data signed: (b) (4) 13 Apr 2021 01:07:16

Generated On: 10 Jun 2021 09:45:50

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	31 MAR 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"/>

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 11:20:56

Generated On: 10 Jun 2021 09:45:50

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 11:20:56

Generated On: 10 Jun 2021 09:45:50

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 MAR 2021	CT ABDOMEN PELVIS WITH IV CONTRAST ONLY	Adverse Event	
31 MAR 2021	1 VIEW PORTABLE AP CHEST XRAY	Adverse Event	

US3752184

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:45:50

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

US3752184

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:45:50

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 ☐

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 17:31:53

Generated On: 10 Jun 2021 09:45:50

SAEID	USA-US113-2021-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 17:31:53

Generated On: 10 Jun 2021 09:45:50

SAEID	USA-US113-2021-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/APR/2021 06:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 17:31:53

Generated On: 10 Jun 2021 09:45:50

SAEID	USA-US113-2021-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/APR/2021 13:46
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

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 17:31:53

Generated On: 10 Jun 2021 09:45:50

SAEID	USA-US113-2021-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 12:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3752184 (Prod: Baptist Health Center for Clinical Research)

US3752184

Form: Participant Creation

Generated On: 10 Jun 2021 09:45:50

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'US3752184'	RWS_ENDPOINT	20 Aug 2020 18:30:01
	ENDPOINT (b) (4)	

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Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:25

US3752184

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:30:02

US3752184

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:25

US3752184

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'SCRN'	System	20 Aug 2020 19:36:25

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Per GCL Lab Reconciliation: Swab: Year of Birth (1939) recorded on this form does not match with the Year of birth (1935) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Oct 2020 12:51:18
Query 'Per GCL Lab Reconciliation: Swab: Year of Birth (1939) recorded on this form does not match with the Year of birth (1935) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'confirmed correct year of birth is 1939' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:25:22
User opened query 'Per GCL Lab Reconciliation: Swab: Year of Birth (1939) recorded on this form does not match with the Year of birth (1935) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:51:32
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:30:03

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '81'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'YEARS'	System	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '81'	System	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:20

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Aug 2020'	System	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2020'	System	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:48

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:30:02

US3752184

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'I'	System	20 Aug 2020 19:36:54

US3752184

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:36:54

US3752184

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:45:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:14:46

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	(b) (4) Coder Import	16 Oct 2020 17:05:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	16 Oct 2020 17:05:38
Data point term sent to Coder	System	16 Oct 2020 16:35:59
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:35:00
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:35:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	(b) (4) Coder Import	21 Aug 2020 16:16:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Aug 2020 16:16:22
Data point term sent to Coder	System	21 Aug 2020 16:15:34
User entered 'COPD'	(b) (4), (b) (6)	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2005'	System	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2005'	System	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered empty.	System	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered empty.	System	21 Aug 2020 16:15:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Per DM CLR – REQUERY: Site response noted; however issue remains. Please update medical history term to include the location of Neuropathy (i.e. arms, legs, etc.) as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:16:02
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy NOS - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:26:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:26:25
Data point term sent to Coder	System	29 Oct 2020 13:21:58
Query 'Per DM CLR – REQUERY: Site response noted; however issue remains. Please update medical history term to include the location of Neuropathy (i.e. arms, legs, etc.) as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:21:41
User entered 'NEUROPATHY (UNKNOWN TYPE & unknown location)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 13:21:31
User opened query 'Per DM CLR – REQUERY: Site response noted; however issue remains. Please update medical history term to include the location of Neuropathy (i.e. arms, legs, etc.) as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:48:09

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:46:32
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.'	(b) (4), (b) (6)	28 Oct 2020 17:20:29
' answered with 'Type of neuropathy is unknown.' (Site from DM).		
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.'	(b) (4), (b) (6)	28 Oct 2020 16:09:57
' (Site from DM).		
Data point term sent to Coder	System	16 Oct 2020 16:35:59
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:35:38
User entered 'NEUROPATHY (unknown type)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:35:38
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 16:17:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Aug 2020 16:17:30
Data point term sent to Coder	System	21 Aug 2020 16:16:37
User entered 'Neuropathy'	(b) (4), (b) (6)	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2017'	System	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2017'	System	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered empty.	System	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered empty.	System	21 Aug 2020 16:16:00

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 16:17:30
Data point term sent to Coder	(b) (4)	
User entered 'Depression'	System	21 Aug 2020 16:16:37
	(b) (4), (b) (6)	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2015'	System	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2015'	System	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered empty.	System	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered empty.	System	21 Aug 2020 16:16:18

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	08 Oct 2020 18:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 18:34:47
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 18:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 18:31:47
Data point term sent to Coder	System	08 Oct 2020 13:32:14
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1)PROSTATE CANCER 2) PROSTATE SURGERY ' (Site from System).	System	08 Oct 2020 13:31:16
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1)PROSTATE CANCER 2) PROSTATE SURGERY ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 13:31:16
Data point term sent to Coder	System	08 Oct 2020 13:31:14
User entered 'PROSTATE CANCER' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 13:31:09
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1)PROSTATE CANCER 2) PROSTATE SURGERY ' (Site from System).	Coder Import (b) (4)	08 Oct 2020 08:24:16

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Aug 2020 16:18:44
User entered 'Prostate cancer with prostate surgery'	(b) (4), (b) (6)	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2012'	System	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2012'	System	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2012'	System	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2012'	System	21 Aug 2020 16:18:33

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 16:20:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:20:19
Data point term sent to Coder	System	21 Aug 2020 16:19:45
User entered 'Melanoma'	(b) (4), (b) (6)	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2018'	System	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2018'	System	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2018'	System	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2018'	System	21 Aug 2020 16:19:00

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatic operation, LLT: Prostate surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 13:08:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:08:17
Data point term sent to Coder	System	08 Oct 2020 13:33:15
User entered 'Prostate surgery for prostate cancer'	(b) (4), (b) (6)	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2012'	System	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2012'	System	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'Jan 2012'	System	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '2012'	System	08 Oct 2020 13:32:20

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '13:40'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered '20 Aug 2020 13:40'	System	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '66.5' in	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:56
DataPoint set to visible.	System	20 Aug 2020 19:36:54

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '173.2' lb	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:56
DataPoint set to visible.	System	20 Aug 2020 19:36:54

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
Amendment Manager: User entered '27.59399'	System	17 Sep 2020 00:16:41
User entered '27.6'	System	21 Aug 2020 16:19:56
DataPoint set to visible.	System	20 Aug 2020 19:36:54

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'kg/m2'	System	21 Aug 2020 16:19:56
DataPoint set to visible.	System	20 Aug 2020 19:36:54

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:27:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:01
User entered '097.8' F	(b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:02:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:36:01
User entered '078'	(b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'bpm'	System	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:36:01
User entered '14'	(b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'breaths/min'	System	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:36:01
User entered '118'	(b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'mmHg'	System	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:36:01
User entered '082'	(b) (4), (b) (6)	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User entered 'mmHg'	System	21 Aug 2020 16:19:56

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36

US3752184

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36

US3752184

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:49:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 19:03:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:20:07

US3752184

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:49:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 19:03:09
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 16:20:07

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Outdoor service provider'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

US3752184

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:21:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:22:28

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:22:28

US3752184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:22:28

US3752184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'VISIT1'	System	21 Aug 2020 16:22:28

US3752184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:55

US3752184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 05:58:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:58:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 19:19:55
User entered '187403' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:23:07

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:23:07

US3752184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:23:07

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:23:07

US3752184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:23:07

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:50

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:28:01
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:49:03

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:06:21
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:42:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:42:22
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:48:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:19
User entered '66.5' in	(b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:42:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:19
User entered '173.2' lb	(b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:06:21
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:42:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:42:22
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:48:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:19
User entered '66.5' in	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:42:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:19
User entered '173.2' lb	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '13:40'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '20 Aug 2020 13:40'	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '97.8' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:28:29
User entered '097.8' F	(b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:25:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 16:25:19
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:25:19
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '78' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:28:29
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:25:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 16:25:19
User entered '078' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:25:19
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'bpm'	System	21 Aug 2020 16:25:19
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:25:19
Query 'Data is required. Please provide.' answered by System	System	21 Aug 2020 16:25:19
data change (Site from System).		21 Aug 2020 16:25:19
User entered '14' reason for change: Data Entry	(b) (4), (b) (6)	21 Aug 2020 16:25:19
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'breaths/min'	System	21 Aug 2020 16:25:19
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:25:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 16:25:19
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:25:19
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Aug 2020 16:25:19
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '82' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:28:29
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:25:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 16:25:19
User entered '082' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:25:19
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Aug 2020 16:25:19
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:06:21
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:42:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:42:22
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:48:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:19
User entered '66.5' in	(b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:42:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:36:19
User entered '173.2' lb	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '15:05'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '20 Aug 2020 15:05'	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:26:05
Query 'Data is required. Please provide.' answered by System	System	21 Aug 2020 16:26:05
data change (Site from System).		21 Aug 2020 16:26:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:26:05
User opened query 'Data is required. Please provide.' (Site from System).		21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:26:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 16:26:05
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:26:05
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'bpm'	System	21 Aug 2020 16:26:05
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:26:05
Query 'Data is required. Please provide.' answered by System	System	21 Aug 2020 16:26:05
data change (Site from System).		21 Aug 2020 16:26:05
User entered '15' reason for change: Data Entry	(b) (4), (b) (6)	21 Aug 2020 16:26:05
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'breaths/min'	System	21 Aug 2020 16:26:05
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:26:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 16:26:05
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:26:05
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Aug 2020 16:26:05
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 16:26:05
Query 'Data is required. Please provide.' answered by System	System	21 Aug 2020 16:26:05
data change (Site from System).		21 Aug 2020 16:26:05
User entered '68' reason for change: Data Entry	(b) (4), (b) (6)	21 Aug 2020 16:26:05
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 16:24:43
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:24:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Aug 2020 16:26:05
User entered empty.	System	21 Aug 2020 16:24:43

US3752184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:36:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:26:18

US3752184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:36:35
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 16:26:18

US3752184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:37:45

US3752184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '14:30'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '20 Aug 2020 14:30'	System	20 Aug 2020 19:37:45

US3752184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'ONCE'	System	20 Aug 2020 19:37:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 19:37:45

US3752184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:26:50

US3752184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:26:50

US3752184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '14:00'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:26:50

US3752184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '20 Aug 2020 14:00'	System	21 Aug 2020 16:26:50

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '13:48'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '20 Aug 2020 13:48'	System	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered empty.	System	21 Aug 2020 16:27:46

US3752184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:27:51

US3752184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '1'	System	21 Aug 2020 16:27:51

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:59:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ad40c8c2-beac-4521-9541-e5a6ce8e1d54'	System	20 Aug 2020 19:59:59
User entered 'Yes (Y)'	System	20 Aug 2020 19:59:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:59:48', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ad40c8c2-beac-4521-9541-e5a6ce8e1d54'	System	20 Aug 2020 19:59:59
User entered '98.2'	System	20 Aug 2020 19:59:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:59:53', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ad40c8c2-beac-4521-9541-e5a6ce8e1d54'	System	20 Aug 2020 19:59:59
User entered 'No (N)'	System	20 Aug 2020 19:59:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:59:56', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ad40c8c2-beac-4521-9541-e5a6ce8e1d54'	System	20 Aug 2020 19:59:59
User entered '20 Aug 2020 14:59'	System	20 Aug 2020 19:59:59

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 14:50'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 17:20'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:10', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa5a8210-ebcc-4706-98a6-35c083877822'	System	21 Aug 2020 01:13:41
User entered 'Yes (Y)'	System	21 Aug 2020 01:13:41

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:31', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa5a8210-ebcc-4706-98a6-35c083877822'	System	21 Aug 2020 01:13:41
User entered '98.4'	System	21 Aug 2020 01:13:41

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:36', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa5a8210-ebcc-4706-98a6-35c083877822'	System	21 Aug 2020 01:13:41
User entered 'No (N)'	System	21 Aug 2020 01:13:41

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:39', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa5a8210-ebcc-4706-98a6-35c083877822'	System	21 Aug 2020 01:13:41
User entered '20 Aug 2020 20:13'	System	21 Aug 2020 01:13:41

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 18:15'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 2'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:21', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '0e572bea-f03e-419f-962f-8edae022b559'	System	22 Aug 2020 01:49:37
User entered 'Yes (Y)'	System	22 Aug 2020 01:49:37

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:26', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '0e572bea-f03e-419f-962f-8edae022b559'	System	22 Aug 2020 01:49:37
User entered '98.3'	System	22 Aug 2020 01:49:37

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:30', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '0e572bea-f03e-419f-962f-8edae022b559'	System	22 Aug 2020 01:49:37
User entered 'No (N)'	System	22 Aug 2020 01:49:37

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:32', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '0e572bea-f03e-419f-962f-8edae022b559'	System	22 Aug 2020 01:49:37
User entered '21 Aug 2020 20:49'	System	22 Aug 2020 01:49:37

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 3'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:14', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992ab163-f1f1-4f0c-857d-e25a087a6032'	System	22 Aug 2020 23:57:26
User entered 'Yes (Y)'	System	22 Aug 2020 23:57:26

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:18', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992ab163-f1f1-4f0c-857d-e25a087a6032'	System	22 Aug 2020 23:57:26
User entered '97.2'	System	22 Aug 2020 23:57:26

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:20', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992ab163-f1f1-4f0c-857d-e25a087a6032'	System	22 Aug 2020 23:57:26
User entered 'No (N)'	System	22 Aug 2020 23:57:26

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:23', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992ab163-f1f1-4f0c-857d-e25a087a6032'	System	22 Aug 2020 23:57:26
User entered '22 Aug 2020 18:57'	System	22 Aug 2020 23:57:26

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 4'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:52:45', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f5f16f86-1e74-4c84-8332-74cf0f27dc13'	System	23 Aug 2020 22:52:58
User entered 'Yes (Y)'	System	23 Aug 2020 22:52:58

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:52:51', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f5f16f86-1e74-4c84-8332-74cf0f27dc13'	System	23 Aug 2020 22:52:58
User entered '98.3'	System	23 Aug 2020 22:52:58

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:52:54', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f5f16f86-1e74-4c84-8332-74cf0f27dc13'	System	23 Aug 2020 22:52:58
User entered 'No (N)'	System	23 Aug 2020 22:52:58

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:52:56', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f5f16f86-1e74-4c84-8332-74cf0f27dc13'	System	23 Aug 2020 22:52:58
User entered '23 Aug 2020 17:52'	System	23 Aug 2020 22:52:58

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 5'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:34', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '52a35cf1-bf4d-44c8-acaf-f1ba92b8914b'	System	25 Aug 2020 00:01:16
User entered 'Yes (Y)'	System	25 Aug 2020 00:01:16

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:01:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '52a35cf1-bf4d-44c8-acaf-f1ba92b8914b'	System	25 Aug 2020 00:01:16
User entered '97.5'	System	25 Aug 2020 00:01:16

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:01:10', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '52a35cf1-bf4d-44c8-acaf-f1ba92b8914b'	System	25 Aug 2020 00:01:16
User entered 'No (N)'	System	25 Aug 2020 00:01:16

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:01:13', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '52a35cf1-bf4d-44c8-acaf-f1ba92b8914b'	System	25 Aug 2020 00:01:16
User entered '24 Aug 2020 19:01'	System	25 Aug 2020 00:01:16

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 6'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:35', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6c700c2f-5d5e-48ed-98bd-87dbe7e437ff'	System	26 Aug 2020 00:11:49
User entered 'Yes (Y)'	System	26 Aug 2020 00:11:49

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:40', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6c700c2f-5d5e-48ed-98bd-87dbe7e437ff'	System	26 Aug 2020 00:11:49
User entered '97.6'	System	26 Aug 2020 00:11:49

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6c700c2f-5d5e-48ed-98bd-87dbe7e437ff'	System	26 Aug 2020 00:11:49
User entered 'No (N)'	System	26 Aug 2020 00:11:49

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:45', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6c700c2f-5d5e-48ed-98bd-87dbe7e437ff'	System	26 Aug 2020 00:11:49
User entered '25 Aug 2020 19:11'	System	26 Aug 2020 00:11:49

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 7'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:32:00', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ba7d7d42-c0ad-4beb-a4ba-f1df923b0563'	System	27 Aug 2020 01:33:39
User entered 'Yes (Y)'	System	27 Aug 2020 01:33:39

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:33:33', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ba7d7d42-c0ad-4beb-a4ba-f1df923b0563'	System	27 Aug 2020 01:33:39
User entered '97.2'	System	27 Aug 2020 01:33:39

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:33:35', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ba7d7d42-c0ad-4beb-a4ba-f1df923b0563'	System	27 Aug 2020 01:33:39
User entered 'No (N)'	System	27 Aug 2020 01:33:39

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:33:37', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ba7d7d42-c0ad-4beb-a4ba-f1df923b0563'	System	27 Aug 2020 01:33:39
User entered '26 Aug 2020 20:33'	System	27 Aug 2020 01:33:39

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T15:00:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '28c7f016-c669-4ad8-a1de-fcc79fba2007'	System	20 Aug 2020 20:00:28
User entered 'None (1)'	System	20 Aug 2020 20:00:28

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T15:00:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '28c7f016-c669-4ad8-a1de-fcc79fba2007'	System	20 Aug 2020 20:00:28
User entered 'No (N)'	System	20 Aug 2020 20:00:28

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T15:00:12', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '28c7f016-c669-4ad8-a1de-fcc79fba2007'	System	20 Aug 2020 20:00:28
User entered 'No (N)'	System	20 Aug 2020 20:00:28

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T15:00:18', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '28c7f016-c669-4ad8-a1de-fcc79fba2007'	System	20 Aug 2020 20:00:28
User entered 'None (1)'	System	20 Aug 2020 20:00:28

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T15:00:23', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '28c7f016-c669-4ad8-a1de-fcc79fba2007'	System	20 Aug 2020 20:00:28
User entered '20 Aug 2020 15:00'	System	20 Aug 2020 20:00:28

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 14:50'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 17:20'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f974c4e6-fea3-4c05-af75-08cb72bd30b6'	System	21 Aug 2020 01:13:58
User entered 'None (1)'	System	21 Aug 2020 01:13:58

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:47', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f974c4e6-fea3-4c05-af75-08cb72bd30b6'	System	21 Aug 2020 01:13:58
User entered 'No (N)'	System	21 Aug 2020 01:13:58

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f974c4e6-fea3-4c05-af75-08cb72bd30b6'	System	21 Aug 2020 01:13:58
User entered 'No (N)'	System	21 Aug 2020 01:13:58

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:52', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f974c4e6-fea3-4c05-af75-08cb72bd30b6'	System	21 Aug 2020 01:13:58
User entered 'None (1)'	System	21 Aug 2020 01:13:58

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:13:55', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f974c4e6-fea3-4c05-af75-08cb72bd30b6'	System	21 Aug 2020 01:13:58
User entered '20 Aug 2020 20:13'	System	21 Aug 2020 01:13:58

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 18:15'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 2'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:36', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e54ab8ca-978e-4ca0-8ece-2868e0d95512'	System	22 Aug 2020 01:49:50
User entered 'None (1)'	System	22 Aug 2020 01:49:50

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:40', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e54ab8ca-978e-4ca0-8ece-2868e0d95512'	System	22 Aug 2020 01:49:50
User entered 'No (N)'	System	22 Aug 2020 01:49:50

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e54ab8ca-978e-4ca0-8ece-2868e0d95512'	System	22 Aug 2020 01:49:50
User entered 'No (N)'	System	22 Aug 2020 01:49:50

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:45', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e54ab8ca-978e-4ca0-8ece-2868e0d95512'	System	22 Aug 2020 01:49:50
User entered 'None (1)'	System	22 Aug 2020 01:49:50

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:48', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e54ab8ca-978e-4ca0-8ece-2868e0d95512'	System	22 Aug 2020 01:49:50
User entered '21 Aug 2020 20:49'	System	22 Aug 2020 01:49:50

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 3'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:27', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a8f16a9c-002a-4397-ad19-709a7561cd7c'	System	22 Aug 2020 23:57:44
User entered 'None (1)'	System	22 Aug 2020 23:57:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:33', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a8f16a9c-002a-4397-ad19-709a7561cd7c'	System	22 Aug 2020 23:57:44
User entered 'No (N)'	System	22 Aug 2020 23:57:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:35', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a8f16a9c-002a-4397-ad19-709a7561cd7c'	System	22 Aug 2020 23:57:44
User entered 'No (N)'	System	22 Aug 2020 23:57:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:38', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a8f16a9c-002a-4397-ad19-709a7561cd7c'	System	22 Aug 2020 23:57:44
User entered 'None (1)'	System	22 Aug 2020 23:57:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:40', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a8f16a9c-002a-4397-ad19-709a7561cd7c'	System	22 Aug 2020 23:57:44
User entered '22 Aug 2020 18:57'	System	22 Aug 2020 23:57:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 4'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:52:59', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f18b8c28-133a-47db-85b7-99e8470c6590'	System	23 Aug 2020 22:53:10
User entered 'None (1)'	System	23 Aug 2020 22:53:10

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f18b8c28-133a-47db-85b7-99e8470c6590'	System	23 Aug 2020 22:53:10
User entered 'No (N)'	System	23 Aug 2020 22:53:10

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:03', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f18b8c28-133a-47db-85b7-99e8470c6590'	System	23 Aug 2020 22:53:10
User entered 'No (N)'	System	23 Aug 2020 22:53:10

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:05', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f18b8c28-133a-47db-85b7-99e8470c6590'	System	23 Aug 2020 22:53:10
User entered 'None (1)'	System	23 Aug 2020 22:53:10

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f18b8c28-133a-47db-85b7-99e8470c6590'	System	23 Aug 2020 22:53:10
User entered '23 Aug 2020 17:53'	System	23 Aug 2020 22:53:10

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 5'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T18:59:57', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '196b55bd-0204-4174-acab-eef809b0af83'	System	25 Aug 2020 00:00:15
User entered 'None (1)'	System	25 Aug 2020 00:00:15

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '196b55bd-0204-4174-acab-eef809b0af83'	System	25 Aug 2020 00:00:15
User entered 'No (N)'	System	25 Aug 2020 00:00:15

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '196b55bd-0204-4174-acab-eef809b0af83'	System	25 Aug 2020 00:00:15
User entered 'No (N)'	System	25 Aug 2020 00:00:15

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:08', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '196b55bd-0204-4174-acab-eef809b0af83'	System	25 Aug 2020 00:00:15
User entered 'None (1)'	System	25 Aug 2020 00:00:15

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:10', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '196b55bd-0204-4174-acab-eef809b0af83'	System	25 Aug 2020 00:00:15
User entered '24 Aug 2020 19:00'	System	25 Aug 2020 00:00:15

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 6'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6e327d47-bf7f-4463-b146-36a4945661df'	System	26 Aug 2020 00:12:01
User entered 'None (1)'	System	26 Aug 2020 00:12:01

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:51', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6e327d47-bf7f-4463-b146-36a4945661df'	System	26 Aug 2020 00:12:01
User entered 'No (N)'	System	26 Aug 2020 00:12:01

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:53', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6e327d47-bf7f-4463-b146-36a4945661df'	System	26 Aug 2020 00:12:01
User entered 'No (N)'	System	26 Aug 2020 00:12:01

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:56', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6e327d47-bf7f-4463-b146-36a4945661df'	System	26 Aug 2020 00:12:01
User entered 'None (1)'	System	26 Aug 2020 00:12:01

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:11:58', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6e327d47-bf7f-4463-b146-36a4945661df'	System	26 Aug 2020 00:12:01
User entered '25 Aug 2020 19:11'	System	26 Aug 2020 00:12:01

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 7'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:32', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2bf9680d-7156-4178-a9a4-7a2737aba5ab'	System	27 Aug 2020 01:31:44
User entered 'None (1)'	System	27 Aug 2020 01:31:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:34', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2bf9680d-7156-4178-a9a4-7a2737aba5ab'	System	27 Aug 2020 01:31:44
User entered 'No (N)'	System	27 Aug 2020 01:31:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:37', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2bf9680d-7156-4178-a9a4-7a2737aba5ab'	System	27 Aug 2020 01:31:44
User entered 'No (N)'	System	27 Aug 2020 01:31:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:39', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2bf9680d-7156-4178-a9a4-7a2737aba5ab'	System	27 Aug 2020 01:31:44
User entered 'None (1)'	System	27 Aug 2020 01:31:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:41', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2bf9680d-7156-4178-a9a4-7a2737aba5ab'	System	27 Aug 2020 01:31:44
User entered '26 Aug 2020 20:31'	System	27 Aug 2020 01:31:44

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:58:26', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered 'None (0)'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:58:38', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered 'None (0)'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:58:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered 'None (0)'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:58:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered 'None (0)'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:58:53', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered 'None (0)'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:58:57', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered 'None (0)'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:59:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f'	System	20 Aug 2020 19:59:13
User entered 'No (N)'	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T14:59:09', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '6df631c7-1f50-4a8a-95ef-b06a091adb2f' User entered '20 Aug 2020 14:59'	System	20 Aug 2020 19:59:13
	System	20 Aug 2020 19:59:13

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 14:50'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 17:20'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:00', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'None (0)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'None (0)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:03', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'None (0)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'None (0)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'None (0)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:09', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'None (0)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:13', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered 'No (N)'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-20T20:14:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f76e2d40-17db-46ef-a968-650d90c69e97'	System	21 Aug 2020 01:14:19
User entered '20 Aug 2020 20:14'	System	21 Aug 2020 01:14:19

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '20 Aug 2020 18:15'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 2'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:52', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'None (0)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:53', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'None (0)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:55', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'None (0)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:57', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'None (0)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:49:59', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'None (0)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:50:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'None (0)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:50:03', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered 'No (N)'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-21T20:50:05', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'f79e3619-c174-490b-bdc6-9c7d1eb1ddac'	System	22 Aug 2020 01:50:08
User entered '21 Aug 2020 20:50'	System	22 Aug 2020 01:50:08

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 3'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'None (0)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:44', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'None (0)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:47', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'None (0)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:48', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'None (0)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:50', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'None (0)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:51', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'None (0)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:53', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered 'No (N)'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-22T18:57:55', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9ad1e5ef-ee56-4b7a-8ba3-83a46b1e84c5'	System	22 Aug 2020 23:58:01
User entered '22 Aug 2020 18:57'	System	22 Aug 2020 23:58:01

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 4'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:10', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'None (0)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:12', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'None (0)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:13', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'None (0)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'None (0)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'None (0)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:18', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'None (0)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:22', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered 'No (N)'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-23T17:53:24', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b9baf540-506f-4447-9df4-d6132ba70cf2'	System	23 Aug 2020 22:53:27
User entered '23 Aug 2020 17:53'	System	23 Aug 2020 22:53:27

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 5'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'None (0)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'None (0)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:19', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'None (0)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:21', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'None (0)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:23', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'None (0)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:24', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'None (0)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:27', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered 'No (N)'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-24T19:00:29', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '70d6b245-e652-4126-85c5-3a1da7c6c2cf'	System	25 Aug 2020 00:00:31
User entered '24 Aug 2020 19:00'	System	25 Aug 2020 00:00:31

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 6'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'None (0)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:03', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'None (0)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:05', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'None (0)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'None (0)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:08', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'None (0)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:10', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'None (0)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered 'No (N)'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-25T19:12:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'e81143d4-faa5-4415-867a-dfcc4ff6fc4b'	System	26 Aug 2020 00:12:20
User entered '25 Aug 2020 19:12'	System	26 Aug 2020 00:12:20

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 7'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:44', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'None (0)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:45', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'None (0)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:47', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'None (0)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:48', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'None (0)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:50', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'None (0)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:52', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'None (0)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:53', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered 'No (N)'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-08-26T20:31:56', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '2eb9c050-1a5f-4222-b1ad-9992ccb50623'	System	27 Aug 2020 01:32:00
User entered '26 Aug 2020 20:31'	System	27 Aug 2020 01:32:00

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:37:45

US3752184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	22 Oct 2020 22:26:51
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '29 Aug 2020'	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 22:26:51
	(b) (4)	

US3752184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Oct 2020 22:26:51

US3752184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 22:26:51
	(b) (4)	

US3752184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:25:17

US3752184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	21 Sep 2020 16:25:17

US3752184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	22 Oct 2020 22:27:13
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '5 Sep 2020'	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 22:27:13
	(b) (4)	

US3752184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Oct 2020 22:27:13

US3752184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 22:27:13
	(b) (4)	

US3752184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:25:25

US3752184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	21 Sep 2020 16:25:25

US3752184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	22 Oct 2020 22:27:02
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	22 Oct 2020 22:27:24
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Oct 2020 22:27:24
User entered '12 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	22 Oct 2020 22:27:24
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	22 Oct 2020 22:27:02
User entered '5 Sep 2020'	System	22 Oct 2020 22:27:02
	Amanda Horn (b) (4)	22 Oct 2020 22:27:02
	(b) (4)	

US3752184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	22 Oct 2020 22:27:02

US3752184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	22 Oct 2020 22:27:02
	(b) (4)	

US3752184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:25:32

US3752184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	21 Sep 2020 16:25:32

US3752184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:25:47

US3752184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:25:47

US3752184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:25:47

US3752184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'VISIT2'	System	21 Sep 2020 16:25:47

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '10:54'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Sep 2020 10:54'	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:06
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:06
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:06
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'bpm'	System	21 Sep 2020 17:30:06
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:06
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:06
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'breaths/min'	System	21 Sep 2020 17:30:06
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:06
User entered '135' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:06
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Sep 2020 17:30:06
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:06
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:06
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Sep 2020 17:30:06
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:53
User entered '11:40' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 17:30:53
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:53
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:30:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:53
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'bpm'	System	21 Sep 2020 17:30:53
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:53
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'breaths/min'	System	21 Sep 2020 17:30:53
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:53
User entered '142' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Sep 2020 17:30:53
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 17:30:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 17:30:53
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:30:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 17:29:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Sep 2020 17:30:53
User entered empty.	System	21 Sep 2020 17:29:45

US3752184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:08

US3752184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:08

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '11:22'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Sep 2020 11:22'	System	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'ONCE'	System	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 16:26:11

US3752184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:33

US3752184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:33

US3752184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '10:55'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:33

US3752184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Sep 2020 10:55'	System	21 Sep 2020 17:31:33

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '10:52'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Sep 2020 10:52'	System	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered empty.	System	21 Sep 2020 17:31:49

US3752184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:31:53

US3752184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	21 Sep 2020 17:31:53

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:42:57', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '1ff2f3b3-c2bf-4af7-b71e-902a84ba7f15'	System	21 Sep 2020 16:43:55
User entered 'Yes (Y)'	System	21 Sep 2020 16:43:55

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:43:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '1ff2f3b3-c2bf-4af7-b71e-902a84ba7f15'	System	21 Sep 2020 16:43:55
User entered '99.0'	System	21 Sep 2020 16:43:55

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:43:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '1ff2f3b3-c2bf-4af7-b71e-902a84ba7f15'	System	21 Sep 2020 16:43:55
User entered 'No (N)'	System	21 Sep 2020 16:43:55

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:43:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '1ff2f3b3-c2bf-4af7-b71e-902a84ba7f15'	System	21 Sep 2020 16:43:55
User entered '21 Sep 2020 11:43'	System	21 Sep 2020 16:43:55

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 11:42'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:05', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22563f64-003d-496e-815a-5c0698869a9b'	System	22 Sep 2020 00:01:44
User entered 'Yes (Y)'	System	22 Sep 2020 00:01:44

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:09', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22563f64-003d-496e-815a-5c0698869a9b'	System	22 Sep 2020 00:01:44
User entered '99.0'	System	22 Sep 2020 00:01:44

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:14', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22563f64-003d-496e-815a-5c0698869a9b'	System	22 Sep 2020 00:01:44
User entered 'No (N)'	System	22 Sep 2020 00:01:44

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:40', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22563f64-003d-496e-815a-5c0698869a9b'	System	22 Sep 2020 00:01:44
User entered '21 Sep 2020 19:01'	System	22 Sep 2020 00:01:44

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 15:07'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 2'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 3'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:36:59', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fb4c9649-80f6-405f-ad3a-af4c9f70da86'	System	23 Sep 2020 23:37:13
User entered 'Yes (Y)'	System	23 Sep 2020 23:37:13

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fb4c9649-80f6-405f-ad3a-af4c9f70da86'	System	23 Sep 2020 23:37:13
User entered '98.7'	System	23 Sep 2020 23:37:13

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:10', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fb4c9649-80f6-405f-ad3a-af4c9f70da86'	System	23 Sep 2020 23:37:13
User entered 'No (N)'	System	23 Sep 2020 23:37:13

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:13', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fb4c9649-80f6-405f-ad3a-af4c9f70da86'	System	23 Sep 2020 23:37:13
User entered '23 Sep 2020 18:37'	System	23 Sep 2020 23:37:13

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 4'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:12', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7dc965fd-1384-42b3-bbe7-fe847f2f2c43'	System	25 Sep 2020 00:57:24
User entered 'Yes (Y)'	System	25 Sep 2020 00:57:24

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7dc965fd-1384-42b3-bbe7-fe847f2f2c43'	System	25 Sep 2020 00:57:24
User entered '98.3'	System	25 Sep 2020 00:57:24

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:18', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7dc965fd-1384-42b3-bbe7-fe847f2f2c43'	System	25 Sep 2020 00:57:24
User entered 'No (N)'	System	25 Sep 2020 00:57:24

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:21', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7dc965fd-1384-42b3-bbe7-fe847f2f2c43'	System	25 Sep 2020 00:57:24
User entered '24 Sep 2020 19:57'	System	25 Sep 2020 00:57:24

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 5'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:22', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ed485923-118a-431c-a513-0d199dc38b14'	System	25 Sep 2020 23:26:37
User entered 'Yes (Y)'	System	25 Sep 2020 23:26:37

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:27', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ed485923-118a-431c-a513-0d199dc38b14'	System	25 Sep 2020 23:26:37
User entered '97.8'	System	25 Sep 2020 23:26:37

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:30', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ed485923-118a-431c-a513-0d199dc38b14'	System	25 Sep 2020 23:26:37
User entered 'No (N)'	System	25 Sep 2020 23:26:37

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:33', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ed485923-118a-431c-a513-0d199dc38b14'	System	25 Sep 2020 23:26:37
User entered '25 Sep 2020 18:26'	System	25 Sep 2020 23:26:37

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 6'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 7'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:05', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '303da392-3604-4f3e-9004-1b20fa76eda4'	System	28 Sep 2020 01:40:18
User entered 'Yes (Y)'	System	28 Sep 2020 01:40:18

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:08', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '303da392-3604-4f3e-9004-1b20fa76eda4' User entered '97.7'	System	28 Sep 2020 01:40:18
	System	28 Sep 2020 01:40:18

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:12', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '303da392-3604-4f3e-9004-1b20fa76eda4'	System	28 Sep 2020 01:40:18
User entered 'No (N)'	System	28 Sep 2020 01:40:18

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '303da392-3604-4f3e-9004-1b20fa76eda4'	System	28 Sep 2020 01:40:18
User entered '27 Sep 2020 20:40'	System	28 Sep 2020 01:40:18

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:43:11', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '69b76721-ebc9-491a-9aec-93d5692a5ff2'	System	21 Sep 2020 16:46:31
User entered 'None (1)'	System	21 Sep 2020 16:46:31

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:43:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '69b76721-ebc9-491a-9aec-93d5692a5ff2'	System	21 Sep 2020 16:46:31
User entered 'No (N)'	System	21 Sep 2020 16:46:31

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:03', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '69b76721-ebc9-491a-9aec-93d5692a5ff2'	System	21 Sep 2020 16:46:31
User entered 'No (N)'	System	21 Sep 2020 16:46:31

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '69b76721-ebc9-491a-9aec-93d5692a5ff2'	System	21 Sep 2020 16:46:31
User entered 'None (1)'	System	21 Sep 2020 16:46:31

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:09', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '69b76721-ebc9-491a-9aec-93d5692a5ff2'	System	21 Sep 2020 16:46:31
User entered '21 Sep 2020 11:44'	System	21 Sep 2020 16:46:31

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 11:42'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '431bf2a5-b531-40f9-a98d-2d821c54cd2e'	System	22 Sep 2020 00:02:07
User entered 'None (1)'	System	22 Sep 2020 00:02:07

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:52', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '431bf2a5-b531-40f9-a98d-2d821c54cd2e'	System	22 Sep 2020 00:02:07
User entered 'No (N)'	System	22 Sep 2020 00:02:07

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:55', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '431bf2a5-b531-40f9-a98d-2d821c54cd2e'	System	22 Sep 2020 00:02:07
User entered 'No (N)'	System	22 Sep 2020 00:02:07

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:01:58', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '431bf2a5-b531-40f9-a98d-2d821c54cd2e'	System	22 Sep 2020 00:02:07
User entered 'None (1)'	System	22 Sep 2020 00:02:07

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:00', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '431bf2a5-b531-40f9-a98d-2d821c54cd2e'	System	22 Sep 2020 00:02:07
User entered '21 Sep 2020 19:02'	System	22 Sep 2020 00:02:07

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 15:07'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 2'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 3'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22754a7c-3cc8-40eb-bad7-cf8ccb13eba7'	System	23 Sep 2020 23:37:29
User entered 'None (1)'	System	23 Sep 2020 23:37:29

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:21', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22754a7c-3cc8-40eb-bad7-cf8ccb13eba7'	System	23 Sep 2020 23:37:29
User entered 'No (N)'	System	23 Sep 2020 23:37:29

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:24', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22754a7c-3cc8-40eb-bad7-cf8ccb13eba7'	System	23 Sep 2020 23:37:29
User entered 'No (N)'	System	23 Sep 2020 23:37:29

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:26', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22754a7c-3cc8-40eb-bad7-cf8ccb13eba7'	System	23 Sep 2020 23:37:29
User entered 'None (1)'	System	23 Sep 2020 23:37:29

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:28', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '22754a7c-3cc8-40eb-bad7-cf8ccb13eba7'	System	23 Sep 2020 23:37:29
User entered '23 Sep 2020 18:37'	System	23 Sep 2020 23:37:29

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 4'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:24', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '38e2b502-d0bf-4cae-998d-35dc0fcb7c2b'	System	25 Sep 2020 00:57:37
User entered 'None (1)'	System	25 Sep 2020 00:57:37

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:26', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '38e2b502-d0bf-4cae-998d-35dc0fcb7c2b'	System	25 Sep 2020 00:57:37
User entered 'No (N)'	System	25 Sep 2020 00:57:37

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:28', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '38e2b502-d0bf-4cae-998d-35dc0fcb7c2b'	System	25 Sep 2020 00:57:37
User entered 'No (N)'	System	25 Sep 2020 00:57:37

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:30', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '38e2b502-d0bf-4cae-998d-35dc0fcb7c2b'	System	25 Sep 2020 00:57:37
User entered 'None (1)'	System	25 Sep 2020 00:57:37

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:32', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '38e2b502-d0bf-4cae-998d-35dc0fcb7c2b'	System	25 Sep 2020 00:57:37
User entered '24 Sep 2020 19:57'	System	25 Sep 2020 00:57:37

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 5'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:37', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992d4445-fc02-4aab-bb8d-f8fe153e7f5d'	System	25 Sep 2020 23:26:49
User entered 'None (1)'	System	25 Sep 2020 23:26:49

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:39', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992d4445-fc02-4aab-bb8d-f8fe153e7f5d'	System	25 Sep 2020 23:26:49
User entered 'No (N)'	System	25 Sep 2020 23:26:49

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:41', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992d4445-fc02-4aab-bb8d-f8fe153e7f5d'	System	25 Sep 2020 23:26:49
User entered 'No (N)'	System	25 Sep 2020 23:26:49

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992d4445-fc02-4aab-bb8d-f8fe153e7f5d'	System	25 Sep 2020 23:26:49
User entered 'None (1)'	System	25 Sep 2020 23:26:49

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:45', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '992d4445-fc02-4aab-bb8d-f8fe153e7f5d'	System	25 Sep 2020 23:26:49
User entered '25 Sep 2020 18:26'	System	25 Sep 2020 23:26:49

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 6'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 7'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:19', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '5a5f983c-26b2-4096-beed-f2f8362d825a'	System	28 Sep 2020 01:40:30
User entered 'None (1)'	System	28 Sep 2020 01:40:30

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:21', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '5a5f983c-26b2-4096-beed-f2f8362d825a'	System	28 Sep 2020 01:40:30
User entered 'No (N)'	System	28 Sep 2020 01:40:30

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:23', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '5a5f983c-26b2-4096-beed-f2f8362d825a'	System	28 Sep 2020 01:40:30
User entered 'No (N)'	System	28 Sep 2020 01:40:30

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:24', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '5a5f983c-26b2-4096-beed-f2f8362d825a'	System	28 Sep 2020 01:40:30
User entered 'None (1)'	System	28 Sep 2020 01:40:30

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:27', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '5a5f983c-26b2-4096-beed-f2f8362d825a'	System	28 Sep 2020 01:40:30
User entered '27 Sep 2020 20:40'	System	28 Sep 2020 01:40:30

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:13', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'None (0)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:14', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'None (0)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'None (0)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:19', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'None (0)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:21', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'None (0)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:23', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'None (0)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:26', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered 'No (N)'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T11:44:29', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'fa697a3e-e3e2-489e-88be-87fca5df0519'	System	21 Sep 2020 16:46:40
User entered '21 Sep 2020 11:44'	System	21 Sep 2020 16:46:40

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 11:42'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'None (0)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'None (0)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'None (0)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:09', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'None (0)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:11', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'None (0)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:12', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'None (0)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered 'No (N)'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-21T19:02:17', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8dc61a37-8cce-4bef-bba2-592706217d66'	System	22 Sep 2020 00:02:20
User entered '21 Sep 2020 19:02'	System	22 Sep 2020 00:02:20

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '21 Sep 2020 15:07'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 2'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 3'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:31', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'None (0)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:33', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'None (0)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:34', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'None (0)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:36', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'None (0)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:37', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'None (0)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:39', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'None (0)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:42', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered 'No (N)'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-23T18:37:44', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '703b151f-fea4-4f60-b46e-7dd49bb4d467'	System	23 Sep 2020 23:37:48
User entered '23 Sep 2020 18:37'	System	23 Sep 2020 23:37:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 4'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:37', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered 'None (0)'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:38', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered 'None (0)'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:40', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered 'None (0)'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:42', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered 'None (0)'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:43', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7' User entered 'None (0)'	System	25 Sep 2020 00:57:51
	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:45', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered 'None (0)'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:47', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered 'No (N)'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-24T19:57:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '7966e9da-613d-411b-a0ed-049de3ba5ab7'	System	25 Sep 2020 00:57:51
User entered '24 Sep 2020 19:57'	System	25 Sep 2020 00:57:51

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 5'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'None (0)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:51', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'None (0)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:54', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'None (0)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:55', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'None (0)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:57', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'None (0)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:26:58', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'None (0)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:27:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered 'No (N)'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-25T18:27:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '103ce145-dbe3-4534-8900-157c52f72b91'	System	25 Sep 2020 23:27:07
User entered '25 Sep 2020 18:27'	System	25 Sep 2020 23:27:07

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 6'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
Data entry locked.	System	21 Sep 2020 16:26:11
User entered 'Day 7'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:30', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'None (0)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:31', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'None (0)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:33', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'None (0)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:35', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'None (0)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:36', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'None (0)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:38', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'None (0)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:40', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered 'No (N)'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-09-27T20:40:42', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'eb39c289-4aef-4ff8-90dc-f8e9e6b7bae8'	System	28 Sep 2020 01:40:45
User entered '27 Sep 2020 20:40'	System	28 Sep 2020 01:40:45

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:26:11

US3752184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:50:48
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:26:11

US3752184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	30 Oct 2020 19:21:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '28 Sep 2020'	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 19:21:57
	(b) (4)	

US3752184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:21:57

US3752184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	30 Oct 2020 19:21:57
	(b) (4)	

US3752184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:55:28

US3752184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	06 Oct 2020 12:55:28

US3752184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:55:43

US3752184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:55:43

US3752184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:55:43

US3752184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:55:43

US3752184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:29:28

US3752184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	12 Oct 2020 17:29:28

US3752184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:29:43

US3752184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:29:43

US3752184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:29:43

US3752184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:29:43

US3752184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:13:52

US3752184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	21 Oct 2020 21:13:52

US3752184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:08

US3752184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:08

US3752184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:08

US3752184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'VISIT3'	System	21 Oct 2020 21:14:08

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '11:25'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Oct 2020 11:25'	System	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '68'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'bpm'	System	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '18'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'breaths/min'	System	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '156'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '68'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'mmHg'	System	21 Oct 2020 21:14:41

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45

US3752184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45

US3752184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:53

US3752184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:53

US3752184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 21OCT2020, however, per GCL, they have an Unscheduled sample collected on 21OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:03:00
Query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 21OCT2020, however, per GCL, they have an Unscheduled sample collected on 21OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' answered with 'it should be visit 3 Day 57' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 20:34:37
User opened query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 21OCT2020, however, per GCL, they have an Unscheduled sample collected on 21OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 14:13:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 21:15:12

US3752184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:15:12

US3752184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '11:34'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:15:12

US3752184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered '21 Oct 2020 11:34'	System	21 Oct 2020 21:15:12

US3752184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:15:16

US3752184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	21 Oct 2020 21:15:16

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 64'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752184

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 71'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752184

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
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US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3752184

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 78'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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)
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US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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US3752184

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Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered 'Day 92'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:45:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 19:37:45

US3752184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:02:37
Data entry locked.	System	20 Aug 2020 19:37:45
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 19:37:45

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:02:37

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:02:37

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:02:37

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2020-12-09T10:13:29', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'd8613de6-1d1c-4ba8-a4bf-9e30b2498e9f'	System	09 Dec 2020 16:13:37
User entered 'No (N)'	System	09 Dec 2020 16:13:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2020-12-09T10:13:32', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'd8613de6-1d1c-4ba8-a4bf-9e30b2498e9f'	System	09 Dec 2020 16:13:37
User entered 'No (N)'	System	09 Dec 2020 16:13:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2020-12-09T10:13:34', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'd8613de6-1d1c-4ba8-a4bf-9e30b2498e9f'	System	09 Dec 2020 16:13:37
User entered '09 Dec 2020 10:13:34'	System	09 Dec 2020 16:13:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-01-13T21:29:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ca770a46-658c-4a75-ae53-a78de138becf'	System	14 Jan 2021 03:29:10
User entered 'No (N)'	System	14 Jan 2021 03:29:10

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-01-13T21:29:03', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ca770a46-658c-4a75-ae53-a78de138becf'	System	14 Jan 2021 03:29:10
User entered 'No (N)'	System	14 Jan 2021 03:29:10

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-01-13T21:29:07', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'ca770a46-658c-4a75-ae53-a78de138becf' User entered '13 Jan 2021 21:29:07'	System	14 Jan 2021 03:29:10

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-01-20T07:09:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a23f56a8-6acf-4858-b6ab-a9043165e9e2'	System	20 Jan 2021 13:09:20
User entered 'No (N)'	System	20 Jan 2021 13:09:20

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-01-20T07:09:12', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a23f56a8-6acf-4858-b6ab-a9043165e9e2'	System	20 Jan 2021 13:09:20
User entered 'No (N)'	System	20 Jan 2021 13:09:20

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-01-20T07:09:15', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'a23f56a8-6acf-4858-b6ab-a9043165e9e2'	System	20 Jan 2021 13:09:20
User entered '20 Jan 2021 07:09:15'	System	20 Jan 2021 13:09:20

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-02-10T19:37:20', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'c1160c4f-ec1b-4440-88d5-7bcd4147191f'	System	11 Feb 2021 01:37:32
User entered 'No (N)'	System	11 Feb 2021 01:37:32

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-02-10T19:37:25', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'c1160c4f-ec1b-4440-88d5-7bcd4147191f'	System	11 Feb 2021 01:37:32
User entered 'No (N)'	System	11 Feb 2021 01:37:32

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-02-10T19:37:28', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'c1160c4f-ec1b-4440-88d5-7bcd4147191f'	System	11 Feb 2021 01:37:32
User entered '10 Feb 2021 19:37:28'	System	11 Feb 2021 01:37:32

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-02-15T02:44:58', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b4eac30a-3d18-4edd-b28e-9c7fd8516a26'	System	15 Feb 2021 08:45:10
User entered 'No (N)'	System	15 Feb 2021 08:45:10

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-02-15T02:45:01', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b4eac30a-3d18-4edd-b28e-9c7fd8516a26'	System	15 Feb 2021 08:45:10
User entered 'No (N)'	System	15 Feb 2021 08:45:10

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-02-15T02:45:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: 'b4eac30a-3d18-4edd-b28e-9c7fd8516a26'	System	15 Feb 2021 08:45:10
User entered '15 Feb 2021 02:45:04'	System	15 Feb 2021 08:45:10

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-02-23T17:09:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '435edba9-558f-4ca4-b565-1c9cfaff522e'	System	23 Feb 2021 23:13:51
User entered 'No (N)'	System	23 Feb 2021 23:13:51

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-02-23T17:09:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '435edba9-558f-4ca4-b565-1c9cfaff522e'	System	23 Feb 2021 23:13:51
User entered 'No (N)'	System	23 Feb 2021 23:13:51

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-02-23T17:09:09', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '435edba9-558f-4ca4-b565-1c9cfaff522e'	System	23 Feb 2021 23:13:51
User entered '23 Feb 2021 17:09:09'	System	23 Feb 2021 23:13:51

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-02-27T18:18:20', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9bb08a3b-0686-419f-89a1-3f2a11bf7e47'	System	28 Feb 2021 00:21:01
User entered 'No (N)'	System	28 Feb 2021 00:21:01

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-02-27T18:18:23', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9bb08a3b-0686-419f-89a1-3f2a11bf7e47'	System	28 Feb 2021 00:21:01
User entered 'No (N)'	System	28 Feb 2021 00:21:01

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-02-27T18:18:26', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '9bb08a3b-0686-419f-89a1-3f2a11bf7e47'	System	28 Feb 2021 00:21:01
User entered '27 Feb 2021 18:18:26'	System	28 Feb 2021 00:21:01

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-03-06T16:13:02', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8064cf8b-9117-4016-ba39-412ca7312889'	System	06 Mar 2021 22:13:09
User entered 'No (N)'	System	06 Mar 2021 22:13:09

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-03-06T16:13:04', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8064cf8b-9117-4016-ba39-412ca7312889'	System	06 Mar 2021 22:13:09
User entered 'No (N)'	System	06 Mar 2021 22:13:09

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-03-06T16:13:06', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '8064cf8b-9117-4016-ba39-412ca7312889'	System	06 Mar 2021 22:13:09
User entered '06 Mar 2021 16:13:06'	System	06 Mar 2021 22:13:09

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[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 (bec774993ec20501)', Time: '2021-03-13T21:37:49', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '01f78172-8cbf-432c-8406-6754b839d421'	System	14 Mar 2021 03:37:56
User entered 'No (N)'	System	14 Mar 2021 03:37:56

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

Have you been exposed to someone with 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 (bec774993ec20501)', Time: '2021-03-13T21:37:52', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '01f78172-8cbf-432c-8406-6754b839d421'	System	14 Mar 2021 03:37:56
User entered 'No (N)'	System	14 Mar 2021 03:37:56

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-03-13T21:37:54', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '01f78172-8cbf-432c-8406-6754b839d421'	System	14 Mar 2021 03:37:56
User entered '13 Mar 2021 21:37:54'	System	14 Mar 2021 03:37:56

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:02:37

US3752184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:37
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:02:37

US3752184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-02-27T18:18:31', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '84d81024-462e-487b-8ccc-fb58e56dd402'	System	28 Feb 2021 00:21:13
User entered 'No (N)'	System	28 Feb 2021 00:21:13

US3752184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bec774993ec20501)', Time: '2021-02-27T18:18:37', User OID: 'PatientReportedOutcome (US3752184)', ODM File OID: '84d81024-462e-487b-8ccc-fb58e56dd402'	System	28 Feb 2021 00:21:13
User entered '27 Feb 2021 18:18:37'	System	28 Feb 2021 00:21:13

US3752184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:15:14

US3752184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:15:14

US3752184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:15:14

US3752184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:15:14

US3752184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:15:18

US3752184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:07:45
User entered 'I'	System	16 Nov 2020 18:15:18

US3752184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'No (N)'	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:14:07
	(b) (4)	

US3752184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	20 Jan 2021 17:14:07
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	20 Jan 2021 17:14:07
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:14:07
	(b) (4)	

US3752184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:14:10
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'I'	System	20 Jan 2021 17:14:10

US3752184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:14:20
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '19 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:14:20
	(b) (4)	

US3752184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:14:20

US3752184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:14:20
	(b) (4)	

US3752184

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:14:23
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'I'	System	20 Jan 2021 17:14:23

US3752184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 20:13:14
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '18 Feb 2021'	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 20:13:14
	(b) (4)	

US3752184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 20:13:14

US3752184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 20:13:14
	(b) (4)	

US3752184

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 20:13:17
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'I'	System	24 Feb 2021 20:13:17

US3752184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:45:28

US3752184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:45:28

US3752184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:45:28

US3752184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'VISIT4'	System	17 Mar 2021 19:45:28

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '17 Mar 2021'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '12:40'	(b) (4)	31 Mar 2021 13:44:29
	Lauren Evans (b) (4)	

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered '17 Mar 2021 12:40'	System	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '98.4' F	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered 'Oral (Oral)'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered empty.	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '83'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'bpm'	System	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '16'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'breaths/min'	System	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '136'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'mmHg'	System	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:17:35
User entered '74'	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'mmHg'	System	31 Mar 2021 13:44:29

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32

US3752184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32

US3752184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:45:36

US3752184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:45:36

US3752184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:46:05

US3752184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:46:05

US3752184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered '12:54'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:46:05

US3752184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered '17 Mar 2021 12:54'	System	17 Mar 2021 19:46:05

US3752184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:46:08

US3752184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:16:32
User entered 'I'	System	17 Mar 2021 19:46:08

US3752184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:26
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	19 Apr 2021 19:48:43
	(b) (4)	

US3752184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:26
	(b) (4)	
User entered '19 Apr 2021'	Timothy Campbell (b) (4)	19 Apr 2021 19:48:43
	(b) (4)	

US3752184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	19 Apr 2021 19:48:43
	(b) (4)	

US3752184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:26
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	19 Apr 2021 19:48:43
	(b) (4)	

US3752184

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:26
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	19 Apr 2021 19:48:48
	(b) (4)	

US3752184

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 19:48:48

US3752184

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:20:42

US3752184

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:20:42

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:20:42

US3752184

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

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 21:20:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:22:40
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:27:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:03:38

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 11:56:03
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:22:40
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:27:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 14:27:32
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 06:14:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:03:38

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:21:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'I'	System	25 Jan 2021 21:21:42

US3752184

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

Form: Unblinding

Generated On: 10 Jun 2021 09:45:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'I'	System	25 Jan 2021 21:21:42

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '168.9' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '79.9' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '28.00835'	System	25 Jan 2021 21:22:59
DataPoint set to visible.	System	25 Jan 2021 21:21:42

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '168.9' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '79.9' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '28.00835'	System	25 Jan 2021 21:22:59
DataPoint set to visible.	System	25 Jan 2021 21:21:42

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '11:51'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '25 Jan 2021 11:51'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '85'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'bpm'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'breaths/min'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '138'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '82'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '168.9' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '79.9' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '28.00835'	System	25 Jan 2021 21:22:59
DataPoint set to visible.	System	25 Jan 2021 21:21:42

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	(b) (4)	25 Jan 2021 21:49:40
User entered '12:48' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:49:40
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	25 Jan 2021 21:22:59
User entered '11:48'	(b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '25 Jan 2021 12:48'	System	25 Jan 2021 21:49:40
User entered '25 Jan 2021 11:48'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '82'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'bpm'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'breaths/min'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '138'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '74'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:22:59

US3752184

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	25 Jan 2021 21:22:59

US3752184

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:42

US3752184

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:42

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

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)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mRNA-1273'	System	25 Jan 2021 21:27:58
DataPoint set to visible.	System	25 Jan 2021 21:21:42

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '12:18'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '25 Jan 2021 12:18'	System	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'ONCE'	System	25 Jan 2021 21:27:58

US3752184

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

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 21:27:58

US3752184

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:20

US3752184

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:20

US3752184

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '12:02'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:20

US3752184

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '25 Jan 2021 12:02'	System	25 Jan 2021 21:28:20

US3752184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:27

US3752184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:27

US3752184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '12:00'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:27

US3752184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:50

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '25 Jan 2021 12:00'	System	25 Jan 2021 21:28:27

US3752184

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

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:33

US3752184

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

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'I'	System	25 Jan 2021 21:28:33

US3752184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 19:16:08
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered '1 Feb 2021'	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 19:16:08
	(b) (4)	

US3752184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Feb 2021 19:16:08

US3752184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 19:16:08
	(b) (4)	

US3752184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:43
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 19:16:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'I'	System	02 Feb 2021 19:16:11

US3752184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '1'	System	02 Feb 2021 19:16:11
DataPoint set to visible.	System	02 Feb 2021 19:16:11

US3752184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:11:37

US3752184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:11:37

US3752184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:11:37

US3752184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'OLD29'	System	26 Feb 2021 19:11:37

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '10:50'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '26 Feb 2021 10:50'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '77'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'bpm'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'breaths/min'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '146'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '84'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '11:50'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '26 Feb 2021 11:50'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '74'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'bpm'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'breaths/min'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '144'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '82'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mmHg'	System	26 Feb 2021 19:12:52

US3752184

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:01

US3752184

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:01

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

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)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'mRNA-1273'	System	26 Feb 2021 19:13:22
DataPoint set to visible.	System	02 Feb 2021 19:16:11

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '11:20'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered '26 Feb 2021 11:20'	System	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'ONCE'	System	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 19:13:22

US3752184

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:13:27

US3752184

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'I'	System	26 Feb 2021 19:13:27

US3752184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:19:08
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	09 Mar 2021 16:23:42
	(b) (4)	

US3752184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:19:08
User entered '5 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	09 Mar 2021 16:23:42
	(b) (4)	

US3752184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:19:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	09 Mar 2021 16:23:42

US3752184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:19:08
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	09 Mar 2021 16:23:42
	(b) (4)	

US3752184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:19:08
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	09 Mar 2021 16:23:46
	(b) (4)	

US3752184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:33
User entered 'I'	System	09 Mar 2021 16:23:46

US3752184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 19:34:24

US3752184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '09 Apr 2021'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:34:24

US3752184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered 'Clinic (Clinic)'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:34:24

US3752184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	09 Apr 2021 19:34:24

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered 'Yes (Y)'	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '09 Apr 2021'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '12:25'	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 12:25'	System	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
	(b) (4)	
User entered '97.8' F	(b) (4), (b) (6)	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered 'Oral (Oral)'	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered empty.	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '98'	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '16'	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '100'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '72'	(b) (4)	09 Apr 2021 19:35:01
	(b) (4), (b) (6)	

US3752184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 19:35:01

US3752184

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:35:52

US3752184

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
	(b) (4)	
User entered '09 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 19:35:52

US3752184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:36:11

US3752184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered '09 Apr 2021'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 19:36:11

US3752184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
	(b) (4)	
User entered '12:34'	(b) (4), (b) (6)	09 Apr 2021 19:36:11

US3752184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 12:34'	System	09 Apr 2021 19:36:11

US3752184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:45:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:56
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
Signature has been broken.	(b) (4)	04 Mar 2021 16:18:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Evans (b) (4)	04 Mar 2021 16:18:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:27:59

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Haematopoietic neoplasms (excl leukaemias and lymphomas), HLT: Myeloproliferative disorders (excl leukaemias), PT: Essential thrombocythaemia, LLT: Essential thrombocythemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:15:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:15:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:30:00
Data point term sent to Coder	System	04 Mar 2021 16:20:49
User entered 'essential thrombocythemia with JAK2 mutation'	Lauren Evans (b) (4) (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '31 Dec 2020'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'None (NONE)'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '1'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 16:20:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 16:20:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Lauren Evans (b) (4)	04 Mar 2021 16:20:41
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 16:20:03
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 16:20:03

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 17:45:48
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered	(b) (4)	02 Apr 2021 13:04:16
'USA-US113-2021-mRNA-1273-P301000007'	System	02 Apr 2021 13:04:16
User entered 'New'	(b) (4), (b) (6)	02 Apr 2021 13:04:16

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Acute diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 17:47:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 17:47:32
	(b) (4)	
Data point term sent to Coder	System	01 Apr 2021 17:46:24
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:46:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:17
	(b) (4)	
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 17:07:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:07:17
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 16:28:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'data updated per query' (Site from Safety). Signature has been broken.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:17
User entered '10 Apr 2021' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:13:58
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). User signature succeeded.	Lauren Evans (b) (4)	12 Apr 2021 17:07:17
User entered empty.	Lauren Evans (b) (4)	12 Apr 2021 17:07:17
	(b) (4), (b) (6)	09 Apr 2021 15:53:51
	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 17:46:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:46:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 14:13:31
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
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 'SUBJECT HAS NOT YET BEEN DISCHARGED' (Site from System).	(b) (4)	
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).	Amanda Horn (b) (4)	01 Apr 2021 17:46:34
User entered '1'	(b) (4)	
	System	01 Apr 2021 17:46:05
	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:24:39
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:24:39
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '1'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '1'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:28:51
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:17
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated' (Site from Safety).	(b) (4)	12 Apr 2021 17:18:53
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 17:07:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:07:17
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:54:23
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	01 Apr 2021 17:46:05
	Amanda Horn (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: could you confirm if "degenerative disc and joint disease from L4 through S1 was present" found on CT was a new finding, or if it should be considered medical history? ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 19:43:44
User closed query 'PV Query: could you confirm subject's use of albuterol as a concomitant medication? ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 19:43:42
Query 'PV Query: could you confirm if "degenerative disc and joint disease from L4 through S1 was present" found on CT was a new finding, or if it should be considered medical history? ' answered with 'Per review, this was a new finding on the CT. Will fill out an AE and have our PI review it then add to EDC. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	27 Apr 2021 15:27:58
Query 'PV Query: could you confirm subject's use of albuterol as a concomitant medication? ' answered with 'Albuterol is listed as a concomitant medication for COPD. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	27 Apr 2021 15:14:15
User opened query 'PV Query: could you confirm if "degenerative disc and joint disease from L4 through S1 was present" found on CT was a new finding, or if it should be considered medical history? ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 14:54:27
User opened query 'PV Query: could you confirm subject's use of albuterol as a concomitant medication? ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 14:54:22
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:52:56
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:52:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Records sent via email today 19 APR 2021 @ 10:12 AM' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Apr 2021 15:13:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'CT Abdomen Pelvis with IV Contrast with findings of uncomplicated diverticulitis. Chest x-ray with no acute cardiopulmonary findings. Records being sent to safety team ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Apr 2021 15:09:17
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 21:24:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 21:24:01
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:28:53
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'these will updated when available' (Site from Safety).	Lauren Evans (b) (4)	12 Apr 2021 17:19:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:54:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:24:39
	(b) (4)	
User entered 'SUBJECT ADMITTED TO HOSPITAL FOR PAIN CONTROL AND IV ANTIBIOTICS. CT OF ABDOMEN SHOWS UNCOMPLICATED DIVERTICULITIS. DISCHARGED HOME ON ORAL ANTIBIOTICS X7 DAYS, SEE CONCOMITANT MEDICATIONS.' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:24:39
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'SUBJECT ADMITTED TO HOSPITAL FOR PAIN CONTROL AND IV ANTIBIOTICS. CT OF ABDOMEN SHOWS UNCOMPLICATED DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:46:05
	(b) (4)	

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 17:46:05

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 17:46:05

US3752184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 17:46:05

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
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: Degeneration of lumbar or lumbosacral intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 17:57:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Apr 2021 17:57:16
	(b) (4)	
Data point term sent to Coder	System	30 Apr 2021 15:46:32
User entered 'Degenerative disc and joint disease L4-S1'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '31 Mar 2021'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'Yes (Y)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Apr 2021 15:46:39
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	30 Apr 2021 15:46:39
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Apr 2021 15:46:04
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '1'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Lauren Evans (b) (4)	30 Apr 2021 15:46:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:28
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 15:46:04

US3752184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 15:46:04

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:45:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:28:06

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 16:17:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 16:17:18
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 16:16:25
Coding entries removed.	(b) (4), (b) (6)	30 Dec 2020 16:16:11
	(b) (4), (b) (6)	
User entered 'GAbAPENTIN' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 16:16:11
	(b) (4), (b) (6)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 12:16:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 12:16:34
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 16:29:14
User entered 'Gaapentin'	(b) (4), (b) (6)	21 Aug 2020 16:28:51
	(b) (4), (b) (6)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Neuropathy'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered '300'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'three times daily (TID)'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'un UNK 2017'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:28:51

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:31:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:31:26
Data point term sent to Coder	System	21 Aug 2020 16:30:16
User entered 'Duloxetine'	(b) (4), (b) (6) (b) (4)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered '60'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'un UNK 2015'	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:29:29

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Oct 2020 17:05:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 17:05:43
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Oct 2020 16:37:00 16 Oct 2020 16:36:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:31:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:31:26
Data point term sent to Coder User entered 'Trelegy'	System (b) (4), (b) (6)	21 Aug 2020 16:30:16 21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Chronic obstructive pulmonary disease'	(b) (4), (b) (6)	16 Oct 2020 16:36:14
reason for change: Data Entry Error		
User entered 'COPD'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered '100/62.5/25' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:58:26
User entered '100/62.5'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User closed query 'per CDM RQ: data not updated, please provide explanation for alternate unit' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:56:11
Query 'per CDM RQ: data not updated, please provide explanation for alternate unit' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:58:39
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 20:58:32
User opened query 'per CDM RQ: data not updated, please provide explanation for alternate unit' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:07:23
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:53:52
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:58:33
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:53:44
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'un UNK 2018'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:30:08

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:03:22
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 20:30:31
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 21:00:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:12:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:12:02
Data point term sent to Coder	System	19 Nov 2020 20:11:07
User entered 'SEASONAL INFLUENZA VACCINATION'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 20:10:57

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'Yes (Y)'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'PREVENTION OF SEASONAL INFLUENZA'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Nov 2020 20:10:57

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '0.5'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'mL (mL)'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered empty.	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'once (ONCE)'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered empty.	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Amanda Horn (b) (4)	19 Nov 2020 20:10:57
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered empty.	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 20:30:16
User entered 'UN Oct 2020'	Jamie Pettus (b) (4)	12 Jan 2021 20:30:16
	(b) (4)	
	Amanda Horn (b) (4)	19 Nov 2020 20:10:57
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '0'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'No (N)'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 20:30:16
User entered 'UN Oct 2020'	Jamie Pettus (b) (4)	12 Jan 2021 20:30:16
	(b) (4)	
	Amanda Horn (b) (4)	19 Nov 2020 20:10:57
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'No (N)'	(b) (4)	19 Nov 2020 20:10:57
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User entered empty.	System	19 Nov 2020 20:10:57

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User entered empty.	System	19 Nov 2020 20:10:57

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:49
User entered empty.	System	19 Nov 2020 20:10:57

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:03:26
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'information updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	12 Jan 2021 20:32:42
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 21:00:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:33:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:33:59
Data point term sent to Coder	System	19 Nov 2020 20:12:08
User entered 'PNEUMONIA VACCINATION'	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 20:11:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'Yes (Y)'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'PREVENTION OF PNEUMONIA'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Nov 2020 20:11:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '0.5'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'mL (mL)'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered empty.	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'once (ONCE)'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered empty.	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Amanda Horn (b) (4)	19 Nov 2020 20:11:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered empty.	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	12 Jan 2021 20:32:31
User entered 'UN Oct 2020'	(b) (4)	
	Amanda Horn (b) (4)	19 Nov 2020 20:11:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '0'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'No (N)'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 20:32:31
User entered 'UN Oct 2020'	Jamie Pettus (b) (4)	12 Jan 2021 20:32:31
	(b) (4)	
	Amanda Horn (b) (4)	19 Nov 2020 20:11:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:44:14
User entered 'No (N)'	(b) (4)	19 Nov 2020 20:11:50
	Amanda Horn (b) (4)	
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User entered empty.	System	19 Nov 2020 20:11:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User entered empty.	System	19 Nov 2020 20:11:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:53
User entered empty.	System	19 Nov 2020 20:11:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:28:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:28:04
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 19:16:37
User entered 'Baby Aspirin'	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Thrombosis prophylaxis'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '81'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'once daily (QD)'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Oral (ORAL)'	(b) (4)	26 Feb 2021 19:16:05
	(b) (4), (b) (6)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '25 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'Yes (Y)'	(b) (4)	26 Feb 2021 19:16:05
	(b) (4), (b) (6)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:30:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 19:16:05

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:52
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder	System	01 Apr 2021 17:49:39
User entered 'MORPHINE'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 17:49:12

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '4'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'other (OTHER)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Q2H PRN'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:11
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:11
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:11
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:11
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:12
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:49:12

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:49:12

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:49:12

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:46:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:46:52
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder	System	01 Apr 2021 17:50:40
User entered 'MORPHINE'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '8'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'other (OTHER)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Q2H PRN'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:26
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:26
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:26
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:26
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:49:50
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:49:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:49:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:49:50

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:41:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:41:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder	System	01 Apr 2021 17:51:41
User entered 'LEVAFLOXACIN IN D5W'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 17:50:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '750'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'once daily (QD)'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:38
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:38
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:38
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:38
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:50:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 17:50:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 17:50:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 17:50:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder	System	01 Apr 2021 17:52:42
User entered 'METRONIDAZOLE'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 17:52:10

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '500'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'other (OTHER)'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Q8H'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:55
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:55
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:18:55
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:18:55
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:52:10
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:52:10

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:52:10

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:52:10

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IODINE;IOHEXOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:23
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder	System	01 Apr 2021 17:59:48
User entered 'IOHEXOL 350MG IODINE/ML'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 17:58:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '75'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mL (mL)'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'once (ONCE)'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 17:58:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:58:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:58:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:58:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:35:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:35:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:40:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:40:01
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder System	System	01 Apr 2021 18:00:50
User entered '0.9% NACL'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 18:00:36

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '500'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mL (mL)'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'once (ONCE)'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:00:36
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:00:36

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:00:36

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:00:36

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:35:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:45:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:45:57
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder System	System	01 Apr 2021 18:03:53
User entered '0.9% NACL'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 18:03:00

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '80'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mL (mL)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'other (OTHER)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Q HOUR'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:19:19
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:19:19
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:19:19
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:19:19
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:00
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:03:00

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:03:00

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:03:00

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 18:05:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:05:37
Data point term sent to Coder	System	01 Apr 2021 18:04:54
User entered 'ONDANSETRON HCL'	Amanda Horn (b) (4) (b) (4)	01 Apr 2021 18:03:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '4'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'once (ONCE)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:03:54
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:03:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:03:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 18:03:54

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: UMECLIDINIUM BROMIDE, PRODUCTSYNONYM: INCRUSE ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 14:50:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 14:50:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:20:56
Data point term sent to Coder	System	01 Apr 2021 18:06:56
User entered 'UMECLIDINIUM [INCRUSE ELLIPTA]'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '62.5'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'ug (ug)'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'once daily (QD)'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:19:43
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:19:43
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
Signature has been broken.	Amanda Horn (b) (4)	08 Apr 2021 18:19:43
	(b) (4)	
User entered '2 Apr 2021' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Apr 2021 18:19:43
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	01 Apr 2021 18:05:58
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:05:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:05:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 18:05:58

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:02:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:02:26
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 18:20:38
User entered 'LEVOFLOXACIN'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '750'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'once daily (QD)'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '3 Apr 2021'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:17
	(b) (4)	
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 17:01:52
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:01:52
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:17
	(b) (4)	
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 17:01:52
	(b) (4)	
User entered '10 Apr 2021' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:01:52
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	08 Apr 2021 18:20:31
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:20:31

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:20:31

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 18:20:31

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:22:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:22:49
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 18:21:40
User entered 'METRONIDAZOLE'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'ACUTE DIVERTICULITIS'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '500'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'mg (mg)'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'three times daily (TID)'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '2 Apr 2021'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:17
	(b) (4)	
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 17:03:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:03:14
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:17
	(b) (4)	
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 17:03:14
	(b) (4)	
User entered '10 Apr 2021' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 17:03:14
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	08 Apr 2021 18:21:11
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Apr 2021 18:21:11

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:21:11

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 18:21:11

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 20:29:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 20:29:56
Data point term sent to Coder	System	08 Apr 2021 18:22:43
User entered 'ALBUTEROL SULFATE 90 MCG/ACTUATION'	Amanda Horn (b) (4) (b) (4)	08 Apr 2021 18:22:32

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '2'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'puff (PUFF)'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'other (OTHER)'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Q4H PRN'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered '0'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	09 Apr 2021 12:40:05
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	08 Apr 2021 18:22:32
	(b) (4)	

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:22:32

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:22:32

US3752184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:22:32

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:45:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:56
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Signature has been broken.	(b) (4)	01 Apr 2021 18:40:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	01 Apr 2021 18:40:40
User signature succeeded.	(b) (4)	06 Mar 2021 00:30:00
User entered 'No (N)'	Priyantha Wijewardane	24 Feb 2021 20:13:23
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:41:14
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'CT ABDOMEN PELVIS WITH IV CONTRAST ONLY'	Amanda Horn (b) (4)	01 Apr 2021 18:41:14
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Adverse Event (AE)'	Amanda Horn (b) (4)	01 Apr 2021 18:41:14
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:50

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:41:14
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:50

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '31 Mar 2021'	Amanda Horn (b) (4)	01 Apr 2021 18:41:34
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '1 VIEW PORTABLE AP CHEST XRAY'	Amanda Horn (b) (4)	01 Apr 2021 18:41:34
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered 'Adverse Event (AE)'	Amanda Horn (b) (4)	01 Apr 2021 18:41:34
	(b) (4)	

US3752184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:50

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	01 Apr 2021 18:41:34
	(b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'USA-US113-2021-MRNA-1273-P301000007'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Priyantha'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Wijewardane'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered '9601 Baptist Health Drive, Medical Tower 1, Suite'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Little Rock'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Arkansas'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	System	09 Apr 2021 17:46:21
	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '72205'	Lauren Evans (b) (4)	02 Apr 2021 19:39:07

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'US'	(b) (4) System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:29:25
User entered '2'	System	09 Apr 2021 17:46:21
User entered '1'	System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'USA-US113-2021-MRNA-1273-P301000007'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Priyantha'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Wijewardane'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered '9601 Baptist Health Drive, Medical Tower 1, Suite'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Little Rock'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Arkansas'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	System	09 Apr 2021 17:46:21
	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '72205'	Lauren Evans (b) (4)	02 Apr 2021 19:39:07

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'US'	(b) (4) System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:29:25
User entered '2'	System	09 Apr 2021 17:46:21
User entered '1'	System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '02/Apr/2021 06:04'	System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:50

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)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered	System	02 Apr 2021 13:04:16
'USA-US113-2021-MRNA-1273-P301000007'		

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Priyantha'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Wijewardane'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered '9601 Baptist Health Drive, Medical Tower 1, Suite'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Little Rock'	(b) (4)	
	Lauren Evans (b) (4)	02 Apr 2021 19:39:07

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Arkansas'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	System	09 Apr 2021 17:46:21
	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
User entered '72205'	Lauren Evans (b) (4)	02 Apr 2021 19:39:07

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'US'	(b) (4) System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:29:25
User entered '2'	System	09 Apr 2021 17:46:21
User entered '1'	System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
	(b) (4)	
User entered '09/Apr/2021 13:46'	System	09 Apr 2021 17:46:21

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:50

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)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:46:21

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'USA-US113-2021-MRNA-1273-P301000007'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Yes (Y)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'No (N)'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Priyantha'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 13:04:26
User entered 'Wijewardane'	System	02 Apr 2021 13:04:16

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered '9601 Baptist Health Drive, Medical Tower 1, Suite'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Little Rock'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	09 Apr 2021 17:46:21
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'Arkansas'	(b) (4)	02 Apr 2021 19:39:07
	Lauren Evans (b) (4)	

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:59
Signature has been broken.	(b) (4)	
User entered empty.	System	09 Apr 2021 17:46:21
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered '72205'	(b) (4)	
	Lauren Evans (b) (4)	02 Apr 2021 19:39:07

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:20:56
User entered 'US'	(b) (4) System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:29:25
User entered '2'	System	09 Apr 2021 17:46:21
User entered '1'	System	02 Apr 2021 13:04:34

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	14 Apr 2021 17:31:53
	(b) (4)	
User entered '13/Apr/2021 12:29'	System	13 Apr 2021 16:29:25

US3752184

Folder: SAE USA-US113-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	14 Apr 2021 17:31:53
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 16:29:25