

US3752402 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

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US3752402

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

[Participant ID](#)

US3752402

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

US3752402

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
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 19:47:57

Generated On: 10 Jun 2021 09:49:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	4 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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 19:47:57

Generated On: 10 Jun 2021 09:49:01

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 19:47:57

Generated On: 10 Jun 2021 09:49:01

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Apr 2021 00:16:04

Generated On: 10 Jun 2021 09:49:01

Condition	MIGRAINE HEADACHES
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) 21 Apr 2021 00:16:04

Generated On: 10 Jun 2021 09:49:01

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1958
Stop Year (derived)	1958

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Apr 2021 00:16:04

Generated On: 10 Jun 2021 09:49:01

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3752402

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Apr 2021 00:16:04

Generated On: 10 Jun 2021 09:49:01

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Apr 2021 00:16:04

Generated On: 10 Jun 2021 09:49:01

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:05
Height (<i>xxx.x</i>)	175 cm
Weight (<i>xxx.x</i>)	168 lb
BMI (<i>xxx.x</i>)	24.93506 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 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 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 19:47:57

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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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:47:57

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 190007

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 19:47:57

Generated On: 10 Jun 2021 09:49:01

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 19:47:57

Generated On: 10 Jun 2021 09:49:01

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)	04 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:05
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 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 19:47:57

Generated On: 10 Jun 2021 09:49:01

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)	04 SEP 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:15
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 19:47:57

Generated On: 10 Jun 2021 09:49:01

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 19:47:57

Generated On: 10 Jun 2021 09:49:01

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 10:40

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 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 SEP 2020
Collection time (00:00-23:59)	10:12 (24 HR)
Collection date and time (derived)	04 SEP 2020 10:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:10	04 SEP 2020 10:10
Nasopharyngeal Swab 2	No		

US3752402

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 11:08

PC Open Date & Time

04 SEP 2020 11:00

PC Close Date & Time

04 SEP 2020 13:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

98.5 °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

04 SEP 2020 21:33

PC Open Date & Time

04 SEP 2020 14:25

PC Close Date & Time

05 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

06 SEP 2020 19:33

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 98.0 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 07 SEP 2020 17:08

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

08 SEP 2020 19:18

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 SEP 2020 13:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 10 SEP 2020 15:47

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 8

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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 11 SEP 2020 13:22

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 17:22

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

04 SEP 2020 11:08

PC Open Date & Time

04 SEP 2020 11:00

PC Close Date & Time

04 SEP 2020 13:30

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

04 SEP 2020 21:34

PC Open Date & Time

04 SEP 2020 14:25

PC Close Date & Time

05 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

05 SEP 2020 19:52

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

06 SEP 2020 19:32

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

07 SEP 2020 17:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

08 SEP 2020 19:16

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

09 SEP 2020 13:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

10 SEP 2020 15:47

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 11:09
PC Open Date & Time	04 SEP 2020 11:00
PC Close Date & Time	04 SEP 2020 13:30

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:35
PC Open Date & Time	04 SEP 2020 14:25
PC Close Date & Time	05 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 ☒

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:53
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

50 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:33
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 ☒

PRODUCTION RELEASE (v12.003

52 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:10
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 ☒

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:16
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 ☒

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EAB) (1725)

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US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 13:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☒

PC Time Stamp

11 SEP 2020 13:22

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

12 SEP 2020 17:21

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☒

PC Time Stamp

13 SEP 2020 14:03

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

14 SEP 2020 14:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 13:23
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 17:20
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 14:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 SEP 2020 14:11
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3752402

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	VISIT2

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

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)	01 OCT 2020
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 08:37
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

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)	01 OCT 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 09:25
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3752402

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 09:09 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 09:09

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

US3752402

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	08:38 (24 HR)
Collection date and time (derived)	01 OCT 2020 08:38

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:36	01 OCT 2020 08:36
Nasopharyngeal Swab 2	No		

US3752402

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

01 OCT 2020 09:31

PC Open Date & Time

01 OCT 2020 09:29

PC Close Date & Time

01 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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	01 OCT 2020 17:29
PC Open Date & Time	01 OCT 2020 12:54
PC Close Date & Time	02 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	02 OCT 2020 12:52
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 OCT 2020 14:34
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 14:42

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

05 OCT 2020 18:27

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 05:25

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

07 OCT 2020 16:21

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

01 OCT 2020 09:31

PC Open Date & Time

01 OCT 2020 09:29

PC Close Date & Time

01 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

01 OCT 2020 17:31

PC Open Date & Time

01 OCT 2020 12:54

PC Close Date & Time

02 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

02 OCT 2020 12:53

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

03 OCT 2020 14:35

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

04 OCT 2020 14:43

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

05 OCT 2020 18:28

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

07 OCT 2020 05:26

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

07 OCT 2020 16:21

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 09:32
PC Open Date & Time	01 OCT 2020 09:29
PC Close Date & Time	01 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 17:32
PC Open Date & Time	01 OCT 2020 12:54
PC Close Date & Time	02 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

102 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:54
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

104 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 14:36
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 ☒

PRODUCTION RELEASE (v12.003

106 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 14:43
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

108 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 18:28
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

110 of 2623

EAB) (1725)

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 05:26
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

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EAB) (1725)

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 16:21
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3752402

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 08:12
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752402

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3752402

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	08:19 (24 HR)
Collection date and time (derived)	30 OCT 2020 08:19

US3752402

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 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	04 NOV 2020 08:41:04
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 06:47:20

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 16:04:55

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 08:03:17

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 DEC 2020 07:47:49
Patient Cloud Open Date & Time	06 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 DEC 2020 05:10:42
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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	20 DEC 2020 07:54:53
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 06:01:13

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 05:48:35

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 06:25:33

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 09:01:50

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

24 JAN 2021 05:08:33

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

31 JAN 2021 06:02:28

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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	07 FEB 2021 17:22:36
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 FEB 2021 13:04:07
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 FEB 2021 15:52:39
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 MAR 2021 15:04:50
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 MAR 2021 18:33:03
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

14 MAR 2021 13:35:55

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 06:35:21

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

31 MAR 2021 18:00:02

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 08:07:42

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 06:20:48

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 05:46:10

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 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	27 APR 2021 12:00:55
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 11:47:00

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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="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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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="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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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="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°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="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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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 <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"/>

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3752402

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:49:01

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 15:19:32

US3752402

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:57

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 16:26:02

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 16:26:02

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 23:22:56

Generated On: 10 Jun 2021 09:49:01

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

Visit date (dd MMM yyyy)	5 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 23:22:56

Generated On: 10 Jun 2021 09:49:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 APR 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 09:10
Temperature (xxx.x)	98.3 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)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752402

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 23:22:56

Generated On: 10 Jun 2021 09:49:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 APR 2021

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

US3752402

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 23:22:55

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 APR 2021

Collection time (00:00-23:59)

09:19 (24 HR)

Collection date and time (derived)

5 APR 2021 09:19

US3752402

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 23:22:55

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:28:59

Generated On: 10 Jun 2021 09:49:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752402

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:28:59

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752402

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752402

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:49:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752402

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

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

Visit date (dd MMM yyyy)	19 JAN 2021
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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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US3752402

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:53:49

Generated On: 10 Jun 2021 09:49:01

Date of updated informed consent (dd MMM yyyy) 19 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3752402

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00-23:59)	14:09 (24 HR)
Collection date and time (derived)	19 JAN 2021 14:09

US3752402

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	14:07
Collection Date and Time (derived)	19 JAN 2021 14:07

US3752402

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

AEID

Adverse event

HEADACHE

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)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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 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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

AEID	USA-US113-2021-MRNA-1273-P30 1000006
Adverse event	HIGH GRADE B-CELL LYMPHOMA
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)	5 FEB 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)	26 FEB 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 type="radio"/> Grade 4 <input checked="" 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	26 FEB 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) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	NEW BASELINE ESTABLISHED WITH DIAGNOSIS OF LYMPHOMA. SUBJECT WILL BE GOING THROUGH 6 ROUNDS OF CHEMOTHERAPY.
Narrative	BIOPSY RESULTS: HIGH GRADE B-CELL LYMPHOMA.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 Apr 2021 11:26:11

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 19:47:55

Generated On: 10 Jun 2021 09:49:01

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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 2005	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 12

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER, CHILLS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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)		1 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 OCT 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR 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 (5)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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)	20 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)		20 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) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication HIGH-GRADE B-CELL
LYMPHOMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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 (7)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication HIGH-GRADE B-CELL
LYMPHOMA

Dose per administration 7.5/325

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 Q6H PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication OXYCODONE/ACETAMINOPHE
N

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 5/325

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 PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication 0.9% NACL

Prophylaxis Yes ☐
No ☒

Indication ROUTINE HYDRATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

PER HOUR

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) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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 (12)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication ROUTINE HYDRATION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

PER HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 FEB 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 (14)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ROCEPHIN IN NACL 0.9%

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="radio"/>
	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)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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 (15)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 26 FEB 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 (16)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ELECTROLYTE-A

Prophylaxis Yes ☐
No ☒

Indication ROUTINE PRE-PROCEDURE
MEDICATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

PER HOUR

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 (16)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="radio"/>
	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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 (17)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ROUTINE PRE-PROCEDURE
MEDICATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ROUTINE PREPROCEDURE
MEDICATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ROUTINE IV FLUSH

Dose per administration 3

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 (20)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 26 FEB 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 (22)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication BUPIVACAINE-EPINEPHRINE
0.5%

Prophylaxis Yes ☐
No ☒

Indication PROCEDURE ANESTHESIA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input checked="" 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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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 (23)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ONDANSETRON HCL

Prophylaxis Yes ☒
No ☐

Indication POSTPROCEDURE PREVENTION
OF NAUSEA, VOMITING

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

Q6H PRN

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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 (24)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 6

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 (24)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 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 (25)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication PREDNISOLONE ACETATE 1%

Prophylaxis Yes ☒
No ☐

Indication POSTPROCEDURE
INFLAMMATION PREVENTION

Dose per administration 1

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

If dose unit is Other, specify GTT

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 (25)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="radio"/>
	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 type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
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 (26)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication PROLENSA [BROMFENAC
OPHTHALMIC SOLUTION 0.07%]

Prophylaxis Yes ☐
No ☒

Indication POSTPROCEDURE
INFLAMMATION

Dose per administration 1

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

If dose unit is Other, specify GTT

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="radio"/>
	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 type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication MOXIFLOXACIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
POSTPROCEDURE INFECTION

Dose per administration 1

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

If dose unit is Other, specify GTT

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="radio"/>
	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 type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B-CELL
LYMPHOMA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE DAILY X5 DAYS
FOLLOWING ROUND OF
CHEMOTHERAPY

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 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="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 (29)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ODANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA AND VOMITING POST
CHEMOTHERAPY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	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)	26 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA AND VOMITING POST
CHEMOTHERAPY

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication PEGFILGRASTIM

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ONCE EVERY 3 WEEKS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 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"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication VINCRISTINE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ONCE EVERY 3 WEEKS

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 (34)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		11 MAR 2021
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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication CYCLOPHOSPHAMIDE

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ONCE EVERY 3 WEEKS

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 (35)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	11 MAR 2021	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication DOXORUBICIN

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ONCE EVERY 3 WEEKS

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 (36)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	11 MAR 2021	
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)		
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 (37)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

Name of Medication RITUXIMAB

Prophylaxis Yes ☐
No ☒

Indication HIGH GRADE B CELL
LYMPHOMA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ONCE EVERY 3 WEEKS

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 (37)

Data signed: (b) (4) 08 Apr 2021 15:05:45

Generated On: 10 Jun 2021 09:49:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		11 MAR 2021
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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Mar 2021 00:41:03

Generated On: 10 Jun 2021 09:49:01

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Mar 2021 16:26:02

Generated On: 10 Jun 2021 09:49:01

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 FEB 2021	CT CHEST ABDOMEN PELVIS WITH IV CONTRAST AND ORAL CONTRAST	Diagnostic	
25 FEB 2021	CHEST RADIOGRAPH	Adverse Event	
26 FEB 2021	CERVICAL LYMPH NODE BIOPSY	Diagnostic	
23 DEC 2020	CATARACT REMOVAL,RIGHT	Medical History	

US3752402

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:49:01

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

US3752402

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:49:01

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 ☐

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

SAEID	USA-US113-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	5

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

SAEID	USA-US113-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	26/FEB/2021 13:05
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

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

SAEID	USA-US113-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

SAEID	USA-US113-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	11/MAR/2021 07:01
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

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

SAEID	USA-US113-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 11:41
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

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 03 Apr 2021 11:26:11

Generated On: 10 Jun 2021 09:49:01

SAEID	USA-US113-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	01/APR/2021 11:07
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

US3752402 (Prod: Baptist Health Center for Clinical Research)

US3752402

Form: Participant Creation

Generated On: 10 Jun 2021 09:49:01

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:04:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'US3752402'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:45

US3752402

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:34:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:45:18

US3752402

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:34:20
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:46

US3752402

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[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 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:34:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 15:45:18

US3752402

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'SCRN'	System	04 Sep 2020 15:45:18

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:47

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '70'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'YEARS'	System	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '70'	System	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered 'Male (M)'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:49:01

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:35:02
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:45:32

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'Sep 2020'	System	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '2020'	System	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 15:45:28

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 14:54:46

US3752402

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:49:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'I'	System	04 Sep 2020 15:45:31

US3752402

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:45:31

US3752402

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:49:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:36:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:46:08

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:47:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:47:50
Data point term sent to Coder	System	08 Sep 2020 16:46:52
User entered 'Migraine headaches'	(b) (4), (b) (6)	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered 'un UNK 2005'	(b) (4), (b) (6)	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'Jan 2005'	System	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '2005'	System	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	08 Sep 2020 16:46:27

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:48:51
Data point term sent to Coder	System	08 Sep 2020 16:47:55
User entered 'Tonsillectomy'	(b) (4), (b) (6)	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered 'un UNK 1958'	(b) (4), (b) (6)	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered 'un UNK 1958'	(b) (4), (b) (6)	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'Jan 1958'	System	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '1958'	System	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'Jan 1958'	System	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '1958'	System	08 Sep 2020 16:47:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:53:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:53:55
Data point term sent to Coder	System	08 Sep 2020 16:53:02
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:13:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Un-verified.	(b) (4), (b) (6)	28 Sep 2020 14:50:16
User entered 'un UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:50:16
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:13:34
User closed query 'per source the start date is 2010. please review. ' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 05:47:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
Query 'per source the start date is 2010. please review. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 14:50:22
DataPoint Un-verified.	(b) (4), (b) (6)	28 Sep 2020 14:50:16
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:50:16
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:38:58
User opened query 'per source the start date is 2010. please review. ' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 02:37:43
User entered '1'	(b) (4), (b) (6)	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:38:58
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'Jan 2010'	System	28 Sep 2020 14:50:16
User entered empty.	System	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '2010'	System	28 Sep 2020 14:50:16
User entered empty.	System	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	08 Sep 2020 16:53:02

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:47
User closed query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:21:32
Query 'please provide source' answered with 'data updated in subject's chart' (Site from CRA).	Lauren Evans (b) (4)	08 Apr 2021 14:16:21
User opened query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:14:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - 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)	01 Oct 2020 20:08:53
Data point term sent to Coder	(b) (4)	
User entered 'Insomnia'	System	01 Oct 2020 20:08:29
	(b) (4), (b) (6)	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:16:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Apr 2021 04:33:13
User closed query 'per source Aug2020 captured. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	18 Apr 2021 04:33:10
Query 'per source Aug2020 captured. please review and clarify' answered with 'data updated per query' (Site from CRA).	Lauren Evans (b) (4)	13 Apr 2021 19:36:31
Signature has been broken.	Lauren Evans (b) (4)	13 Apr 2021 19:36:10
User entered 'UN Aug 2020' reason for change: Data Entry Error	Lauren Evans (b) (4)	13 Apr 2021 19:36:10
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:47
User opened query 'per source Aug2020 captured. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:22:32
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 15:05:45
Signature has been broken.	(b) (4) Lauren Evans (b) (4)	08 Apr 2021 14:15:44
User entered 'un UNK 2020' reason for change: Data Entry Error	Lauren Evans (b) (4)	08 Apr 2021 14:15:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:47
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 15:05:45
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	08 Apr 2021 14:15:59
Signature has been broken.	Lauren Evans	08 Apr 2021 14:15:59
User entered '0' reason for change: Data Entry Error	Lauren Evans	08 Apr 2021 14:15:59
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	08 Apr 2021 14:15:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:22:47
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'Aug 2020'	System	13 Apr 2021 19:36:10
User entered 'Jan 2020'	System	08 Apr 2021 14:15:44
User entered empty.	System	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '2020'	System	08 Apr 2021 14:15:44
User entered empty.	System	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	01 Oct 2020 20:08:13

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:16:09
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Mar 2021 18:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:36:40
Data point term sent to Coder	System	09 Mar 2021 18:36:18
User entered 'BILATERAL CATARACTS'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:16:13
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:16:15
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered 'l'	(b) (4) Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:16:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:16:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:16:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered empty.	System	09 Mar 2021 18:35:22

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered '10:05'	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '04 Sep 2020 10:05'	System	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered '175' cm	(b) (4), (b) (6)	08 Sep 2020 16:47:36
DataPoint set to visible.	System	04 Sep 2020 15:45:31

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered '168' lb	(b) (4), (b) (6)	08 Sep 2020 16:47:36
DataPoint set to visible.	System	04 Sep 2020 15:45:31

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered '24.93506'	System	08 Sep 2020 16:47:36
DataPoint set to visible.	System	04 Sep 2020 15:45:31

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'kg/m2'	System	08 Sep 2020 16:47:36
DataPoint set to visible.	System	04 Sep 2020 15:45:31

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'bpm'	System	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'breaths/min'	System	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'mmHg'	System	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:41:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User entered 'mmHg'	System	08 Sep 2020 16:47:36

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35

US3752402

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35

US3752402

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:12:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'per source the PE was completed. (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:37:58
Query 'per source the PE was completed. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 14:50:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:50:41
DataPoint Un-verified.	(b) (4), (b) (6)	28 Sep 2020 02:44:02
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:43:56
User opened query 'per source the PE was completed. ' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 02:43:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:58:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:47:45

US3752402

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:12:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:50:41
DataPoint Un-verified.	(b) (4), (b) (6)	28 Sep 2020 02:44:09
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:44:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Sep 2020 02:44:05
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:43:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:58:37
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:47:45

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'retired'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

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 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'l'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:49:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:48:38

US3752402

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:45:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:48:55

US3752402

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:45:34
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:48:55

US3752402

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:45:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 16:48:55

US3752402

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'VISIT1'	System	08 Sep 2020 16:48:55

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 15:31:10

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered '190007'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 15:31:10

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 15:31:10

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

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)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:49:07

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

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)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:49:07

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:49:07

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:49:07

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:46:08
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:49:07

US3752402

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:49:01

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:56
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:36:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:04:37
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:23:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:23:01

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered '10:05'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered '04 Sep 2020 10:05'	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered '98.4' F	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:49:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:49:53
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:49:53
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:49:53
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'bpm'	System	08 Sep 2020 16:49:53
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:49:53
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:49:53
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'breaths/min'	System	08 Sep 2020 16:49:53
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:49:53
User entered '132' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:49:53
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'mmHg'	System	08 Sep 2020 16:49:53
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:49:53
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:49:53
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'mmHg'	System	08 Sep 2020 16:49:53
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:49:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:49:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:50:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:50:31
User entered '11:15' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered '04 Sep 2020 11:15'	System	08 Sep 2020 16:50:31
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:50:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:50:31
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:50:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:50:31
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'bpm'	System	08 Sep 2020 16:50:31
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:50:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:50:31
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'breaths/min'	System	08 Sep 2020 16:50:31
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:50:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:50:31
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'mmHg'	System	08 Sep 2020 16:50:31
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:25
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:50:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 16:50:31
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:50:31
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 16:49:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:10
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'mmHg'	System	08 Sep 2020 16:50:31
User entered empty.	System	08 Sep 2020 16:49:34

US3752402

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:50
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:50:40

US3752402

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 02:49:50
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:50:40

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

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)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '10:40'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered '4 Sep 2020 10:40'	System	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'ONCE'	System	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 15:45:53

US3752402

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:51:01

US3752402

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:17:47
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:51:01

US3752402

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:17:47
User entered '10:12'	(b) (4), (b) (6)	08 Sep 2020 16:51:01

US3752402

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:21
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered '04 Sep 2020 10:12'	System	08 Sep 2020 16:51:01

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:49:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:18:08
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:18:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:18:20
User entered '10:10'	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered '04 Sep 2020 10:10'	System	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:18:20
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:18:20
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered empty.	System	08 Sep 2020 16:51:15

US3752402

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 03:18:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:51:20

US3752402

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'l'	System	08 Sep 2020 16:51:20

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:07:44', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '87a58fe8-d2f2-4a81-89d8-a8299d765362' User entered 'Yes (Y)'	System	04 Sep 2020 16:08:16
	System	04 Sep 2020 16:08:16

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:07:53', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '87a58fe8-d2f2-4a81-89d8-a8299d765362' User entered '97.9'	System	04 Sep 2020 16:08:16
	System	04 Sep 2020 16:08:16

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:07:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '87a58fe8-d2f2-4a81-89d8-a8299d765362'	System	04 Sep 2020 16:08:16
User entered 'No (N)'	System	04 Sep 2020 16:08:16

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '87a58fe8-d2f2-4a81-89d8-a8299d765362' User entered '04 Sep 2020 11:08'	System	04 Sep 2020 16:08:16
	System	04 Sep 2020 16:08:16

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 11:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 13:30'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:33:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '510ca83d-e48f-4415-9526-d0aa57657513' User entered 'Yes (Y)'	System	05 Sep 2020 02:33:33
	System	05 Sep 2020 02:33:33

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:33:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '510ca83d-e48f-4415-9526-d0aa57657513' User entered '98.5'	System	05 Sep 2020 02:33:33
	System	05 Sep 2020 02:33:33

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:33:21', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '510ca83d-e48f-4415-9526-d0aa57657513' User entered 'No (N)'	System	05 Sep 2020 02:33:33
	System	05 Sep 2020 02:33:33

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:33:26', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '510ca83d-e48f-4415-9526-d0aa57657513' User entered '04 Sep 2020 21:33'	System	05 Sep 2020 02:33:33
	System	05 Sep 2020 02:33:33

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 14:25'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 2'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:51:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'c6a84678-00f8-4ece-abe9-c61fe84a4048'	System	06 Sep 2020 00:51:54
User entered 'Yes (Y)'	System	06 Sep 2020 00:51:54

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:51:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'c6a84678-00f8-4ece-abe9-c61fe84a4048' User entered '98.7'	System	06 Sep 2020 00:51:54
	System	06 Sep 2020 00:51:54

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:51:44', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'c6a84678-00f8-4ece-abe9-c61fe84a4048'	System	06 Sep 2020 00:51:54
User entered 'No (N)'	System	06 Sep 2020 00:51:54

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:51:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'c6a84678-00f8-4ece-abe9-c61fe84a4048'	System	06 Sep 2020 00:51:54
User entered '05 Sep 2020 19:51'	System	06 Sep 2020 00:51:54

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 3'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:32:53', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dbd3e812-a37f-4cbe-8a5f-546e3003db9f' User entered 'Yes (Y)'	System	07 Sep 2020 00:33:07
	System	07 Sep 2020 00:33:07

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:32:58', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dbd3e812-a37f-4cbe-8a5f-546e3003db9f' User entered '98.7'	System	07 Sep 2020 00:33:07
	System	07 Sep 2020 00:33:07

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:01', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dbd3e812-a37f-4cbe-8a5f-546e3003db9f' User entered 'No (N)'	System	07 Sep 2020 00:33:07
	System	07 Sep 2020 00:33:07

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dbd3e812-a37f-4cbe-8a5f-546e3003db9f' User entered '06 Sep 2020 19:33'	System	07 Sep 2020 00:33:07
	System	07 Sep 2020 00:33:07

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 4'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0cdfb988-c933-4182-b032-42f3d96dcc49' User entered 'Yes (Y)'	System	07 Sep 2020 22:08:56
	System	07 Sep 2020 22:08:56

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:19', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0cdfb988-c933-4182-b032-42f3d96dcc49' User entered '98.0'	System	07 Sep 2020 22:08:56
	System	07 Sep 2020 22:08:56

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:38', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0cdfb988-c933-4182-b032-42f3d96dcc49'	System	07 Sep 2020 22:08:56
User entered 'Yes (Y)'	System	07 Sep 2020 22:08:56

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:52:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:34:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0cdfb988-c933-4182-b032-42f3d96dcc49'	System	07 Sep 2020 22:08:56
User entered '1'	System	07 Sep 2020 22:08:56

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0cdfb988-c933-4182-b032-42f3d96dcc49' User entered '0'	System	07 Sep 2020 22:08:56
	System	07 Sep 2020 22:08:56

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0cdfb988-c933-4182-b032-42f3d96dcc49'	System	07 Sep 2020 22:08:56
User entered '07 Sep 2020 17:08'	System	07 Sep 2020 22:08:56

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 5'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:17:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76f0b9a3-5ef7-4a9d-82d9-adfce85a8252'	System	09 Sep 2020 00:18:44
User entered 'Yes (Y)'	System	09 Sep 2020 00:18:44

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:18:30', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76f0b9a3-5ef7-4a9d-82d9-adfce85a8252'	System	09 Sep 2020 00:18:44
User entered '98.4'	System	09 Sep 2020 00:18:44

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:18:37', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76f0b9a3-5ef7-4a9d-82d9-adfce85a8252'	System	09 Sep 2020 00:18:44
User entered 'No (N)'	System	09 Sep 2020 00:18:44

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:18:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76f0b9a3-5ef7-4a9d-82d9-adfce85a8252'	System	09 Sep 2020 00:18:44
User entered '08 Sep 2020 19:18'	System	09 Sep 2020 00:18:44

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 6'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:11', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '05e95088-ddb3-49c4-90a0-81305f4d4214' User entered 'Yes (Y)'	System	09 Sep 2020 18:20:40
	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '05e95088-ddb3-49c4-90a0-81305f4d4214' User entered '98.3'	System	09 Sep 2020 18:20:40
	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '05e95088-ddb3-49c4-90a0-81305f4d4214'	System	09 Sep 2020 18:20:40
User entered 'Yes (Y)'	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:52:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '05e95088-ddb3-49c4-90a0-81305f4d4214'	System	09 Sep 2020 18:20:40
User entered '1'	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '05e95088-ddb3-49c4-90a0-81305f4d4214' User entered '0'	System	09 Sep 2020 18:20:40
	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:38', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '05e95088-ddb3-49c4-90a0-81305f4d4214' User entered '09 Sep 2020 13:20'	System	09 Sep 2020 18:20:40
	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 7'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:46:38', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '85acfe4b-3eab-4da2-ae33-df27b28204a6' User entered 'Yes (Y)'	System	10 Sep 2020 20:47:09
	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:46:44', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '85acfe4b-3eab-4da2-ae33-df27b28204a6' User entered '98.7'	System	10 Sep 2020 20:47:09
	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:46:50', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '85acfe4b-3eab-4da2-ae33-df27b28204a6'	System	10 Sep 2020 20:47:09
User entered 'Yes (Y)'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:53:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:35:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:46:58', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '85acfe4b-3eab-4da2-ae33-df27b28204a6'	System	10 Sep 2020 20:47:09
User entered '1'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:46:58', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '85acfe4b-3eab-4da2-ae33-df27b28204a6' User entered '0'	System	10 Sep 2020 20:47:09
	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:47:03', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '85acfe4b-3eab-4da2-ae33-df27b28204a6' User entered '10 Sep 2020 15:47'	System	10 Sep 2020 20:47:09
	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	09 Sep 2020 18:20:40
User entered 'Day 8'	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:21:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'af8c8925-8584-43cd-8c94-6acd1a3a4a98' User entered 'Yes (Y)'	System	11 Sep 2020 18:22:30
	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:21:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'af8c8925-8584-43cd-8c94-6acd1a3a4a98' User entered '98.7'	System	11 Sep 2020 18:22:30
	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:22:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'af8c8925-8584-43cd-8c94-6acd1a3a4a98'	System	11 Sep 2020 18:22:30
User entered 'Yes (Y)'	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:53:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:36:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:22:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'af8c8925-8584-43cd-8c94-6acd1a3a4a98'	System	11 Sep 2020 18:22:30
User entered '1'	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:22:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'af8c8925-8584-43cd-8c94-6acd1a3a4a98' User entered '0'	System	11 Sep 2020 18:22:30
	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:22:23', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'af8c8925-8584-43cd-8c94-6acd1a3a4a98' User entered '11 Sep 2020 13:22'	System	11 Sep 2020 18:22:30
	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:20:40

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	10 Sep 2020 20:47:09
User entered 'Day 9'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:21:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f05c0a5b-e0b0-40cc-8bf1-955e1ccdd9db' User entered 'Yes (Y)'	System	12 Sep 2020 22:22:11
	System	12 Sep 2020 22:22:11

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:22:02', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f05c0a5b-e0b0-40cc-8bf1-955e1ccdd9db' User entered '98.6'	System	12 Sep 2020 22:22:11
	System	12 Sep 2020 22:22:11

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:22:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f05c0a5b-e0b0-40cc-8bf1-955e1ccdd9db'	System	12 Sep 2020 22:22:11
User entered 'No (N)'	System	12 Sep 2020 22:22:11

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:22:09', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f05c0a5b-e0b0-40cc-8bf1-955e1ccdd9db' User entered '12 Sep 2020 17:22'	System	12 Sep 2020 22:22:11
	System	12 Sep 2020 22:22:11

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31df47a3-e4fc-428a-b3f8-50d863ca16d3'	System	04 Sep 2020 16:08:44
User entered 'None (1)'	System	04 Sep 2020 16:08:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:26', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31df47a3-e4fc-428a-b3f8-50d863ca16d3'	System	04 Sep 2020 16:08:44
User entered 'No (N)'	System	04 Sep 2020 16:08:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:30', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31df47a3-e4fc-428a-b3f8-50d863ca16d3'	System	04 Sep 2020 16:08:44
User entered 'No (N)'	System	04 Sep 2020 16:08:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:37', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31df47a3-e4fc-428a-b3f8-50d863ca16d3'	System	04 Sep 2020 16:08:44
User entered 'None (1)'	System	04 Sep 2020 16:08:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31df47a3-e4fc-428a-b3f8-50d863ca16d3' User entered '04 Sep 2020 11:08'	System	04 Sep 2020 16:08:44
	System	04 Sep 2020 16:08:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 11:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 13:30'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:33:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7dd57263-ba95-41f7-9b74-c224cbee1421'	System	05 Sep 2020 02:34:55
User entered 'None (1)'	System	05 Sep 2020 02:34:55

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:34:34', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7dd57263-ba95-41f7-9b74-c224cbee1421' User entered 'No (N)'	System	05 Sep 2020 02:34:55
	System	05 Sep 2020 02:34:55

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:34:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7dd57263-ba95-41f7-9b74-c224cbee1421' User entered 'No (N)'	System	05 Sep 2020 02:34:55
	System	05 Sep 2020 02:34:55

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:34:47', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7dd57263-ba95-41f7-9b74-c224cbee1421'	System	05 Sep 2020 02:34:55
User entered 'None (1)'	System	05 Sep 2020 02:34:55

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:34:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7dd57263-ba95-41f7-9b74-c224cbee1421' User entered '04 Sep 2020 21:34'	System	05 Sep 2020 02:34:55
	System	05 Sep 2020 02:34:55

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 14:25'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 2'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:25', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6a6bc985-1b6c-4885-ba8e-897374a4f28c' User entered 'None (1)'	System	06 Sep 2020 00:52:33
	System	06 Sep 2020 00:52:33

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:51:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6a6bc985-1b6c-4885-ba8e-897374a4f28c' User entered 'No (N)'	System	06 Sep 2020 00:52:33
	System	06 Sep 2020 00:52:33

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6a6bc985-1b6c-4885-ba8e-897374a4f28c' User entered 'No (N)'	System	06 Sep 2020 00:52:33
	System	06 Sep 2020 00:52:33

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6a6bc985-1b6c-4885-ba8e-897374a4f28c' User entered 'None (1)'	System	06 Sep 2020 00:52:33
	System	06 Sep 2020 00:52:33

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:28', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6a6bc985-1b6c-4885-ba8e-897374a4f28c' User entered '05 Sep 2020 19:52'	System	06 Sep 2020 00:52:33
	System	06 Sep 2020 00:52:33

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 3'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:32:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '92b00beb-72e0-48a7-91ab-e36317480710'	System	07 Sep 2020 00:32:44
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 00:32:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:31:59', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '92b00beb-72e0-48a7-91ab-e36317480710' User entered 'No (N)'	System	07 Sep 2020 00:32:44
	System	07 Sep 2020 00:32:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:32:35', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '92b00beb-72e0-48a7-91ab-e36317480710' User entered 'No (N)'	System	07 Sep 2020 00:32:44
	System	07 Sep 2020 00:32:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:32:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '92b00beb-72e0-48a7-91ab-e36317480710'	System	07 Sep 2020 00:32:44
User entered 'None (1)'	System	07 Sep 2020 00:32:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:32:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '92b00beb-72e0-48a7-91ab-e36317480710' User entered '06 Sep 2020 19:32'	System	07 Sep 2020 00:32:44
	System	07 Sep 2020 00:32:44

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 4'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:08:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '3470646a-6e81-4bf6-b93d-b9808909ecff' User entered 'None (1)'	System	07 Sep 2020 22:09:21
	System	07 Sep 2020 22:09:21

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '3470646a-6e81-4bf6-b93d-b9808909ecff' User entered 'No (N)'	System	07 Sep 2020 22:09:21
	System	07 Sep 2020 22:09:21

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:03', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '3470646a-6e81-4bf6-b93d-b9808909ecff' User entered 'No (N)'	System	07 Sep 2020 22:09:21
	System	07 Sep 2020 22:09:21

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:09', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '3470646a-6e81-4bf6-b93d-b9808909ecff' User entered 'None (1)'	System	07 Sep 2020 22:09:21
	System	07 Sep 2020 22:09:21

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '3470646a-6e81-4bf6-b93d-b9808909ecff' User entered '07 Sep 2020 17:09'	System	07 Sep 2020 22:09:21
	System	07 Sep 2020 22:09:21

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 5'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:37', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '561b00aa-f602-4656-8ced-b1e835f3a91b' User entered 'None (1)'	System	09 Sep 2020 00:16:52
	System	09 Sep 2020 00:16:52

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '561b00aa-f602-4656-8ced-b1e835f3a91b' User entered 'No (N)'	System	09 Sep 2020 00:16:52
	System	09 Sep 2020 00:16:52

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:43', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '561b00aa-f602-4656-8ced-b1e835f3a91b' User entered 'No (N)'	System	09 Sep 2020 00:16:52
	System	09 Sep 2020 00:16:52

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:46', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '561b00aa-f602-4656-8ced-b1e835f3a91b' User entered 'None (1)'	System	09 Sep 2020 00:16:52
	System	09 Sep 2020 00:16:52

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:50', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '561b00aa-f602-4656-8ced-b1e835f3a91b' User entered '08 Sep 2020 19:16'	System	09 Sep 2020 00:16:52
	System	09 Sep 2020 00:16:52

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 6'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:43', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4bb0e1a5-8702-40a0-8230-40185ac77075'	System	09 Sep 2020 18:21:11
User entered 'None (1)'	System	09 Sep 2020 18:21:11

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:46', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4bb0e1a5-8702-40a0-8230-40185ac77075' User entered 'No (N)'	System	09 Sep 2020 18:21:11
	System	09 Sep 2020 18:21:11

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4bb0e1a5-8702-40a0-8230-40185ac77075' User entered 'No (N)'	System	09 Sep 2020 18:21:11
	System	09 Sep 2020 18:21:11

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4bb0e1a5-8702-40a0-8230-40185ac77075'	System	09 Sep 2020 18:21:11
User entered 'None (1)'	System	09 Sep 2020 18:21:11

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4bb0e1a5-8702-40a0-8230-40185ac77075' User entered '09 Sep 2020 13:20'	System	09 Sep 2020 18:21:11
	System	09 Sep 2020 18:21:11

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 7'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:47:08', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f7211c06-89c4-4106-bab4-fb04b8cff872'	System	10 Sep 2020 20:47:23
User entered 'None (1)'	System	10 Sep 2020 20:47:23

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:47:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f7211c06-89c4-4106-bab4-fb04b8cff872'	System	10 Sep 2020 20:47:23
User entered 'No (N)'	System	10 Sep 2020 20:47:23

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:47:15', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f7211c06-89c4-4106-bab4-fb04b8cff872'	System	10 Sep 2020 20:47:23
User entered 'No (N)'	System	10 Sep 2020 20:47:23

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:47:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f7211c06-89c4-4106-bab4-fb04b8cff872'	System	10 Sep 2020 20:47:23
User entered 'None (1)'	System	10 Sep 2020 20:47:23

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:47:21', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f7211c06-89c4-4106-bab4-fb04b8cff872'	System	10 Sep 2020 20:47:23
User entered '10 Sep 2020 15:47'	System	10 Sep 2020 20:47:23

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:47', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'None (0)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'None (0)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:55', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'None (0)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'None (0)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:08:59', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'None (0)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:09:01', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'None (0)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:09:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered 'No (N)'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T11:09:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76275e1c-eeb5-4e66-9803-7914e6e27e8d' User entered '04 Sep 2020 11:09'	System	04 Sep 2020 16:09:09
	System	04 Sep 2020 16:09:09

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 11:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 13:30'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:34:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'None (0)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'None (0)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:03', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'None (0)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'None (0)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:08', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'None (0)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'None (0)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered 'No (N)'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-04T21:35:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4d73cb77-a765-4b01-9255-7e50e20f3ef8' User entered '04 Sep 2020 21:35'	System	05 Sep 2020 02:35:24
	System	05 Sep 2020 02:35:24

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Sep 2020 14:25'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 2'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:34', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered 'None (0)'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229'	System	06 Sep 2020 00:53:15
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:45', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered 'None (0)'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:55', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered 'None (0)'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:52:58', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered 'None (0)'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:53:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered 'None (0)'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:53:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered 'No (N)'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-05T19:53:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a0340817-7abe-4ec2-a3e6-035885ece229' User entered '05 Sep 2020 19:53'	System	06 Sep 2020 00:53:15
	System	06 Sep 2020 00:53:15

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 3'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'None (0)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:14', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'None (0)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'None (0)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:20', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'None (0)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'None (0)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:24', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'None (0)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbdd654822' User entered 'No (N)'	System	07 Sep 2020 00:33:31
	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-06T19:33:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1bceb716-5f72-4395-813a-9edbddd654822'	System	07 Sep 2020 00:33:31
User entered '06 Sep 2020 19:33'	System	07 Sep 2020 00:33:31

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 4'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:51', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64'	System	07 Sep 2020 22:10:13
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:53', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered 'None (0)'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:55', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered 'None (0)'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered 'None (0)'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:09:59', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered 'None (0)'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:10:01', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered 'None (0)'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:10:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered 'No (N)'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-07T17:10:11', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4ad9851a-dcd4-4cf3-958a-faabfaee0b64' User entered '07 Sep 2020 17:10'	System	07 Sep 2020 22:10:13
	System	07 Sep 2020 22:10:13

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 5'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:09', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'None (0)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:11', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'None (0)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:15', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'None (0)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'None (0)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:19', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'None (0)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'None (0)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:28', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered 'No (N)'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-08T19:16:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd9df33f7-a3de-4ac8-890a-f86de8a843bb' User entered '08 Sep 2020 19:16'	System	09 Sep 2020 00:16:38
	System	09 Sep 2020 00:16:38

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 6'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7'	System	09 Sep 2020 18:20:10
User entered 'No interference with activity (1)'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:36', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered 'None (0)'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:39', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered 'None (0)'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered 'None (0)'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:43', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered 'None (0)'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:45', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered 'None (0)'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:19:50', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered 'No (N)'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-09T13:20:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fe17330c-919d-4911-a068-25b935ee52f7' User entered '09 Sep 2020 13:20'	System	09 Sep 2020 18:20:10
	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 7'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:03', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635'	System	10 Sep 2020 20:48:29
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered 'None (0)'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:08', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered 'None (0)'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered 'None (0)'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered 'None (0)'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:14', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered 'None (0)'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered 'No (N)'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-10T15:48:24', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '20a00a54-c480-4e4a-94e9-b8678776b635' User entered '10 Sep 2020 15:48'	System	10 Sep 2020 20:48:29
	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	09 Sep 2020 18:20:10
User entered 'Day 8'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:49:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:22:49', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7f97ea42-e14d-464d-b80c-8897c51b5253'	System	11 Sep 2020 18:22:58
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		11 Sep 2020 18:22:58

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:22:56', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '7f97ea42-e14d-464d-b80c-8897c51b5253'	System	11 Sep 2020 18:22:58
User entered '11 Sep 2020 13:22'	System	11 Sep 2020 18:22:58

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	10 Sep 2020 20:48:29
User entered 'Day 9'	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:49:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:21:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '83d81365-c29f-4552-8b20-391cc4940829'	System	12 Sep 2020 22:21:08
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:21:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '83d81365-c29f-4552-8b20-391cc4940829' User entered '12 Sep 2020 17:21'	System	12 Sep 2020 22:21:08
	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:48:29

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	11 Sep 2020 18:22:58
User entered 'Day 10'	System	11 Sep 2020 18:22:58

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:49:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-13T14:03:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a2e6dc58-95bc-4590-ab4f-83f3efddc618'	System	13 Sep 2020 19:06:25
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		13 Sep 2020 19:06:25

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-13T14:03:08', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a2e6dc58-95bc-4590-ab4f-83f3efddc618'	System	13 Sep 2020 19:06:25
User entered '13 Sep 2020 14:03'	System	13 Sep 2020 19:06:25

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:22:58

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:22:58

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	12 Sep 2020 22:21:08
User entered 'Day 11'	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 09:49:01

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-14T14:11:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '18afa25e-f044-40a6-a824-ff133580822a' User entered 'None (0)'	System	14 Sep 2020 19:11:31
	System	14 Sep 2020 19:11:31

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-14T14:11:25', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '18afa25e-f044-40a6-a824-ff133580822a' User entered '14 Sep 2020 14:11'	System	14 Sep 2020 19:11:31
	System	14 Sep 2020 19:11:31

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	09 Sep 2020 18:20:10
User entered 'Day 8'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:23:02', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f437d693-de3d-4158-94c7-3f43f34df830'	System	11 Sep 2020 18:23:14
User entered 'No (N)'	System	11 Sep 2020 18:23:14

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-11T13:23:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f437d693-de3d-4158-94c7-3f43f34df830'	System	11 Sep 2020 18:23:14
User entered '11 Sep 2020 13:23'	System	11 Sep 2020 18:23:14

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:20:10

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	10 Sep 2020 20:47:09
User entered 'Day 9'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:20:47', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8f62e9f5-9eab-4796-ab51-8589b4fe0370' User entered 'No (N)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-12T17:20:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8f62e9f5-9eab-4796-ab51-8589b4fe0370' User entered '12 Sep 2020 17:20'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:47:09

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	11 Sep 2020 18:22:30
User entered 'Day 10'	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-13T14:03:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6c74121-8641-4cb9-8513-ee18a845bfb3' User entered 'No (N)'	System	13 Sep 2020 19:06:32
	System	13 Sep 2020 19:06:32

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-13T14:03:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6c74121-8641-4cb9-8513-ee18a845bfb3' User entered '13 Sep 2020 14:03'	System	13 Sep 2020 19:06:32
	System	13 Sep 2020 19:06:32

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:22:30

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	12 Sep 2020 22:21:08
User entered 'Day 11'	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-14T14:11:31', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b707a264-6c19-434d-a727-c84520a854a6' User entered 'No (N)'	System	14 Sep 2020 19:11:37
	System	14 Sep 2020 19:11:37

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-09-14T14:11:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b707a264-6c19-434d-a727-c84520a854a6' User entered '14 Sep 2020 14:11'	System	14 Sep 2020 19:11:37
	System	14 Sep 2020 19:11:37

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 22:21:08

US3752402

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 22:21:08

US3752402

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:30:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:15:30

US3752402

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:30:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '11 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:15:30

US3752402

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:30:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:15:30

US3752402

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:30:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:15:30

US3752402

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:30:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:14:34

US3752402

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'l'	System	23 Sep 2020 19:14:34

US3752402

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:41:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:14:56

US3752402

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:41:08
User closed query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:41:05
Query 'please provide source' answered with 'Corrected ' (Site from CRA).	Haylee Rowe (b) (4)	10 Mar 2021 22:07:47
User opened query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:31:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:14:56

US3752402

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:41:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:14:56

US3752402

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:41:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:14:56

US3752402

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:32:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:13:30

US3752402

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:35:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:19:32
User entered 'l'	System	01 Oct 2020 14:13:30

US3752402

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:32:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:46:30

US3752402

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:32:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:46:30

US3752402

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:32:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:46:30

US3752402

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:32:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:46:30

US3752402

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:52:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:13:38

US3752402

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	01 Oct 2020 14:13:38

US3752402

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:04:55

US3752402

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:04:55

US3752402

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:04:55

US3752402

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'VISIT2'	System	01 Oct 2020 20:04:55

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '08:37'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '01 Oct 2020 08:37'	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:05:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:05:44
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:05:44
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:05:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:05:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:05:44
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:05:44
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'bpm'	System	01 Oct 2020 20:05:44
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:05:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:05:44
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:05:44
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'breaths/min'	System	01 Oct 2020 20:05:44
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:05:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:05:44
User entered '126' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:05:44
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'mmHg'	System	01 Oct 2020 20:05:44
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:05:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:05:44
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:05:44
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'mmHg'	System	01 Oct 2020 20:05:44
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:34:30
Query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile' answered with 'Site miscalculated time vitals were to be obtained.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:41:04
User opened query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:40:47
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:06:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 20:06:34
User entered '09:25' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:06:34
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '01 Oct 2020 09:25'	System	01 Oct 2020 20:06:34
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:06:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:06:34
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:06:34
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:06:34
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:06:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:06:34
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:06:34
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'bpm'	System	01 Oct 2020 20:06:34
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:06:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:06:34
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:06:34
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'breaths/min'	System	01 Oct 2020 20:06:34
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:06:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:06:34
User entered '128' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:06:34
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'mmHg'	System	01 Oct 2020 20:06:34
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 20:06:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 20:06:34
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:06:34
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 20:05:18
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'mmHg'	System	01 Oct 2020 20:06:34
User entered empty.	System	01 Oct 2020 20:05:18

US3752402

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:06:48

US3752402

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:45:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:06:48

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

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)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '09:09'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '1 Oct 2020 09:09'	System	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:43:53
User entered 'ONCE'	System	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:49:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 14:14:04

US3752402

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:48:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:11

US3752402

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:48:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:11

US3752402

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:48:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '08:38'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:11

US3752402

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '01 Oct 2020 08:38'	System	01 Oct 2020 20:07:11

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:49:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:47:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:47:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:47:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '08:36'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:49:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '01 Oct 2020 08:36'	System	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:47:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:47:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered empty.	System	01 Oct 2020 20:07:27

US3752402

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:48:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:07:33

US3752402

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	01 Oct 2020 20:07:33

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:08', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '99f3f882-46ac-40cc-ad1e-9f118052a90d' User entered 'Yes (Y)'	System	01 Oct 2020 14:31:27
	System	01 Oct 2020 14:31:27

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:14', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '99f3f882-46ac-40cc-ad1e-9f118052a90d' User entered '98.2'	System	01 Oct 2020 14:31:27
	System	01 Oct 2020 14:31:27

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '99f3f882-46ac-40cc-ad1e-9f118052a90d'	System	01 Oct 2020 14:31:27
User entered 'No (N)'	System	01 Oct 2020 14:31:27

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:23', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '99f3f882-46ac-40cc-ad1e-9f118052a90d' User entered '01 Oct 2020 09:31'	System	01 Oct 2020 14:31:27
	System	01 Oct 2020 14:31:27

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 09:29'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:29:09', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31dd4368-c750-4fe4-a5c1-bcdba5956825' User entered 'Yes (Y)'	System	01 Oct 2020 22:29:33
	System	01 Oct 2020 22:29:33

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:29:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31dd4368-c750-4fe4-a5c1-bcdba5956825' User entered '99.0'	System	01 Oct 2020 22:29:33
	System	01 Oct 2020 22:29:33

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:29:21', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31dd4368-c750-4fe4-a5c1-bcdba5956825'	System	01 Oct 2020 22:29:33
User entered 'No (N)'	System	01 Oct 2020 22:29:33

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:29:30', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '31dd4368-c750-4fe4-a5c1-bcdba5956825' User entered '01 Oct 2020 17:29'	System	01 Oct 2020 22:29:33
	System	01 Oct 2020 22:29:33

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 12:54'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 2'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:51:47', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94bc042c-e27b-47d8-81ca-2e445d4522ca' User entered 'Yes (Y)'	System	02 Oct 2020 17:52:24
	System	02 Oct 2020 17:52:24

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:01', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94bc042c-e27b-47d8-81ca-2e445d4522ca' User entered '100.7'	System	02 Oct 2020 17:52:24
	System	02 Oct 2020 17:52:24

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94bc042c-e27b-47d8-81ca-2e445d4522ca' User entered 'Yes (Y)'	System	02 Oct 2020 17:52:24
	System	02 Oct 2020 17:52:24

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Site will confirm with subject and update EDC/Source accordingly.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:15:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 15:47:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94bc042c-e27b-47d8-81ca-2e445d4522ca'	System	02 Oct 2020 17:52:24
User entered '1'	System	02 Oct 2020 17:52:24

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94bc042c-e27b-47d8-81ca-2e445d4522ca' User entered '0'	System	02 Oct 2020 17:52:24
	System	02 Oct 2020 17:52:24

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94bc042c-e27b-47d8-81ca-2e445d4522ca' User entered '02 Oct 2020 12:52'	System	02 Oct 2020 17:52:24
	System	02 Oct 2020 17:52:24

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 3'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bcc13955-eb36-48ed-9f3a-0cf1ac8df2a9' User entered 'Yes (Y)'	System	03 Oct 2020 19:34:48
	System	03 Oct 2020 19:34:48

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bcc13955-eb36-48ed-9f3a-0cf1ac8df2a9' User entered '99.7'	System	03 Oct 2020 19:34:48
	System	03 Oct 2020 19:34:48

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:37', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bcc13955-eb36-48ed-9f3a-0cf1ac8df2a9'	System	03 Oct 2020 19:34:48
User entered 'Yes (Y)'	System	03 Oct 2020 19:34:48

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Site will confirm with subject and update EDC/Source accordingly.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:15:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 15:47:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:43', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bcc13955-eb36-48ed-9f3a-0cf1ac8df2a9'	System	03 Oct 2020 19:34:48
User entered '1'	System	03 Oct 2020 19:34:48

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:43', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bcc13955-eb36-48ed-9f3a-0cf1ac8df2a9' User entered '0'	System	03 Oct 2020 19:34:48
	System	03 Oct 2020 19:34:48

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:46', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bcc13955-eb36-48ed-9f3a-0cf1ac8df2a9' User entered '03 Oct 2020 14:34'	System	03 Oct 2020 19:34:48
	System	03 Oct 2020 19:34:48

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 4'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:42:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ca2bf414-9f4a-4b23-af5e-f69fe6633f23'	System	04 Oct 2020 19:42:25
User entered 'Yes (Y)'	System	04 Oct 2020 19:42:25

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:42:11', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ca2bf414-9f4a-4b23-af5e-f69fe6633f23'	System	04 Oct 2020 19:42:25
User entered '98.2'	System	04 Oct 2020 19:42:25

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:42:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ca2bf414-9f4a-4b23-af5e-f69fe6633f23'	System	04 Oct 2020 19:42:25
User entered 'No (N)'	System	04 Oct 2020 19:42:25

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:42:21', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ca2bf414-9f4a-4b23-af5e-f69fe6633f23'	System	04 Oct 2020 19:42:25
User entered '04 Oct 2020 14:42'	System	04 Oct 2020 19:42:25

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 5'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:27:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76fd6cad-127c-40b8-b8f9-a6e439dd9d9f' User entered 'Yes (Y)'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:27:47', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76fd6cad-127c-40b8-b8f9-a6e439dd9d9f' User entered '98.8'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:27:50', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76fd6cad-127c-40b8-b8f9-a6e439dd9d9f' User entered 'No (N)'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:27:54', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '76fd6cad-127c-40b8-b8f9-a6e439dd9d9f' User entered '05 Oct 2020 18:27'	System	05 Oct 2020 23:27:59
	System	05 Oct 2020 23:27:59

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 6'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:25:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b4221a57-f624-4e69-b4bf-e5854e27a270' User entered 'Yes (Y)'	System	07 Oct 2020 10:25:37
	System	07 Oct 2020 10:25:37

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:25:26', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b4221a57-f624-4e69-b4bf-e5854e27a270' User entered '97.7'	System	07 Oct 2020 10:25:37
	System	07 Oct 2020 10:25:37

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:25:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b4221a57-f624-4e69-b4bf-e5854e27a270' User entered 'No (N)'	System	07 Oct 2020 10:25:37
	System	07 Oct 2020 10:25:37

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:25:34', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b4221a57-f624-4e69-b4bf-e5854e27a270' User entered '07 Oct 2020 05:25'	System	07 Oct 2020 10:25:37
	System	07 Oct 2020 10:25:37

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 7'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:20:58', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9b09a0-e489-4421-9bf0-0279ddd68b4f' User entered 'Yes (Y)'	System	07 Oct 2020 21:21:21
	System	07 Oct 2020 21:21:21

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9b09a0-e489-4421-9bf0-0279ddd68b4f' User entered '97.7'	System	07 Oct 2020 21:21:21
	System	07 Oct 2020 21:21:21

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9b09a0-e489-4421-9bf0-0279ddd68b4f' User entered 'No (N)'	System	07 Oct 2020 21:21:21
	System	07 Oct 2020 21:21:21

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9b09a0-e489-4421-9bf0-0279ddd68b4f' User entered '07 Oct 2020 16:21'	System	07 Oct 2020 21:21:21
	System	07 Oct 2020 21:21:21

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:34', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e176e26d-f8cf-4565-93b6-c922f13fa7f6'	System	01 Oct 2020 14:31:53
User entered 'None (1)'	System	01 Oct 2020 14:31:53

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:38', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e176e26d-f8cf-4565-93b6-c922f13fa7f6' User entered 'No (N)'	System	01 Oct 2020 14:31:53
	System	01 Oct 2020 14:31:53

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e176e26d-f8cf-4565-93b6-c922f13fa7f6'	System	01 Oct 2020 14:31:53
User entered 'No (N)'	System	01 Oct 2020 14:31:53

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:45', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e176e26d-f8cf-4565-93b6-c922f13fa7f6' User entered 'None (1)'	System	01 Oct 2020 14:31:53
	System	01 Oct 2020 14:31:53

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e176e26d-f8cf-4565-93b6-c922f13fa7f6' User entered '01 Oct 2020 09:31'	System	01 Oct 2020 14:31:53
	System	01 Oct 2020 14:31:53

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 09:29'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:30:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6426b5f-37aa-4468-ac3b-2caea3d821b3'	System	01 Oct 2020 22:31:15
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 22:31:15

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:30:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6426b5f-37aa-4468-ac3b-2caea3d821b3' User entered 'No (N)'	System	01 Oct 2020 22:31:15
	System	01 Oct 2020 22:31:15

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:30:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6426b5f-37aa-4468-ac3b-2caea3d821b3' User entered 'No (N)'	System	01 Oct 2020 22:31:15
	System	01 Oct 2020 22:31:15

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:30:59', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6426b5f-37aa-4468-ac3b-2caea3d821b3'	System	01 Oct 2020 22:31:15
User entered 'None (1)'	System	01 Oct 2020 22:31:15

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:31:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6426b5f-37aa-4468-ac3b-2caea3d821b3' User entered '01 Oct 2020 17:31'	System	01 Oct 2020 22:31:15
	System	01 Oct 2020 22:31:15

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 12:54'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 2'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:54', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd5add26a-a8f9-4451-8966-96910d55885e'	System	02 Oct 2020 17:53:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	02 Oct 2020 17:53:42

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:52:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd5add26a-a8f9-4451-8966-96910d55885e' User entered 'No (N)'	System	02 Oct 2020 17:53:42
	System	02 Oct 2020 17:53:42

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:53:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd5add26a-a8f9-4451-8966-96910d55885e' User entered 'No (N)'	System	02 Oct 2020 17:53:42
	System	02 Oct 2020 17:53:42

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:53:30', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd5add26a-a8f9-4451-8966-96910d55885e' User entered 'None (1)'	System	02 Oct 2020 17:53:42
	System	02 Oct 2020 17:53:42

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:53:40', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd5add26a-a8f9-4451-8966-96910d55885e' User entered '02 Oct 2020 12:53'	System	02 Oct 2020 17:53:42
	System	02 Oct 2020 17:53:42

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 3'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:34:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dc027982-63c4-497f-bb96-f6f2a188b0e3'	System	03 Oct 2020 19:35:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Oct 2020 19:35:23

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dc027982-63c4-497f-bb96-f6f2a188b0e3' User entered 'No (N)'	System	03 Oct 2020 19:35:23
	System	03 Oct 2020 19:35:23

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dc027982-63c4-497f-bb96-f6f2a188b0e3' User entered 'No (N)'	System	03 Oct 2020 19:35:23
	System	03 Oct 2020 19:35:23

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dc027982-63c4-497f-bb96-f6f2a188b0e3' User entered 'None (1)'	System	03 Oct 2020 19:35:23
	System	03 Oct 2020 19:35:23

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dc027982-63c4-497f-bb96-f6f2a188b0e3' User entered '03 Oct 2020 14:35'	System	03 Oct 2020 19:35:23
	System	03 Oct 2020 19:35:23

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 4'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:42:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8bacbebb-2df6-4b6d-ba71-53e091638d90'	System	04 Oct 2020 19:43:19
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 19:43:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:42:51', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8bacbebb-2df6-4b6d-ba71-53e091638d90' User entered 'No (N)'	System	04 Oct 2020 19:43:19
	System	04 Oct 2020 19:43:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8bacbebb-2df6-4b6d-ba71-53e091638d90' User entered 'No (N)'	System	04 Oct 2020 19:43:19
	System	04 Oct 2020 19:43:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8bacbebb-2df6-4b6d-ba71-53e091638d90'	System	04 Oct 2020 19:43:19
User entered 'None (1)'	System	04 Oct 2020 19:43:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8bacbebb-2df6-4b6d-ba71-53e091638d90' User entered '04 Oct 2020 14:43'	System	04 Oct 2020 19:43:19
	System	04 Oct 2020 19:43:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 5'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6bcc909b-7eb8-4615-828d-3071f4bab81f' User entered 'None (1)'	System	05 Oct 2020 23:28:19
	System	05 Oct 2020 23:28:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6bcc909b-7eb8-4615-828d-3071f4bab81f' User entered 'No (N)'	System	05 Oct 2020 23:28:19
	System	05 Oct 2020 23:28:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6bcc909b-7eb8-4615-828d-3071f4bab81f' User entered 'No (N)'	System	05 Oct 2020 23:28:19
	System	05 Oct 2020 23:28:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6bcc909b-7eb8-4615-828d-3071f4bab81f' User entered 'None (1)'	System	05 Oct 2020 23:28:19
	System	05 Oct 2020 23:28:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '6bcc909b-7eb8-4615-828d-3071f4bab81f' User entered '05 Oct 2020 18:28'	System	05 Oct 2020 23:28:19
	System	05 Oct 2020 23:28:19

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 6'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f605f022-950d-44f8-a3c6-4544d88e3107'	System	07 Oct 2020 10:26:29
User entered 'None (1)'	System	07 Oct 2020 10:26:29

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f605f022-950d-44f8-a3c6-4544d88e3107' User entered 'No (N)'	System	07 Oct 2020 10:26:29
	System	07 Oct 2020 10:26:29

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:19', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f605f022-950d-44f8-a3c6-4544d88e3107' User entered 'No (N)'	System	07 Oct 2020 10:26:29
	System	07 Oct 2020 10:26:29

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f605f022-950d-44f8-a3c6-4544d88e3107'	System	07 Oct 2020 10:26:29
User entered 'None (1)'	System	07 Oct 2020 10:26:29

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:25', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'f605f022-950d-44f8-a3c6-4544d88e3107'	System	07 Oct 2020 10:26:29
User entered '07 Oct 2020 05:26'	System	07 Oct 2020 10:26:29

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 7'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:21', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '28059dd9-7320-48a0-bf69-2ad11c23746e' User entered 'None (1)'	System	07 Oct 2020 21:21:36
	System	07 Oct 2020 21:21:36

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:24', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '28059dd9-7320-48a0-bf69-2ad11c23746e' User entered 'No (N)'	System	07 Oct 2020 21:21:36
	System	07 Oct 2020 21:21:36

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '28059dd9-7320-48a0-bf69-2ad11c23746e' User entered 'No (N)'	System	07 Oct 2020 21:21:36
	System	07 Oct 2020 21:21:36

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:31', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '28059dd9-7320-48a0-bf69-2ad11c23746e' User entered 'None (1)'	System	07 Oct 2020 21:21:36
	System	07 Oct 2020 21:21:36

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:34', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '28059dd9-7320-48a0-bf69-2ad11c23746e' User entered '07 Oct 2020 16:21'	System	07 Oct 2020 21:21:36
	System	07 Oct 2020 21:21:36

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:56', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'None (0)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:31:58', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'None (0)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:32:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'None (0)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:32:02', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'None (0)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:32:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'None (0)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:32:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'None (0)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:32:09', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered 'No (N)'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T09:32:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '184e9ce5-6321-4582-96ee-1dd518d2d7bf' User entered '01 Oct 2020 09:32'	System	01 Oct 2020 14:32:16
	System	01 Oct 2020 14:32:16

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 09:29'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:31:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab' User entered 'None (0)'	System	01 Oct 2020 22:32:26
	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:31:28', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab'	System	01 Oct 2020 22:32:26
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:31:55', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab' User entered 'None (0)'	System	01 Oct 2020 22:32:26
	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:31:59', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab' User entered 'None (0)'	System	01 Oct 2020 22:32:26
	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:32:01', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab' User entered 'None (0)'	System	01 Oct 2020 22:32:26
	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:32:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab'	System	01 Oct 2020 22:32:26
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:32:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab' User entered 'No (N)'	System	01 Oct 2020 22:32:26
	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-01T17:32:24', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e14498a6-2af5-46b3-b141-684a2bf081ab' User entered '01 Oct 2020 17:32'	System	01 Oct 2020 22:32:26
	System	01 Oct 2020 22:32:26

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '01 Oct 2020 12:54'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 2'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:53:51', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334'	System	02 Oct 2020 17:54:35
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:02', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334'	System	02 Oct 2020 17:54:35
User entered 'Some interference with activity (2)'	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:06', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334'	System	02 Oct 2020 17:54:35
User entered 'Some interference with activity (2)'	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334'	System	02 Oct 2020 17:54:35
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334' User entered 'None (0)'	System	02 Oct 2020 17:54:35
	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:21', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334'	System	02 Oct 2020 17:54:35
User entered 'Some interference with activity not requiring medical attention (2)'	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334'	System	02 Oct 2020 17:54:35
User entered 'No (N)'	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-02T12:54:32', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '1ac4c35f-ae84-49e6-ba07-483daf6e0334' User entered '02 Oct 2020 12:54'	System	02 Oct 2020 17:54:35
	System	02 Oct 2020 17:54:35

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 3'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5'	System	03 Oct 2020 19:36:12
User entered 'No interference with activity (1)'	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:37', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5'	System	03 Oct 2020 19:36:12
User entered 'No interference with activity (1)'	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:44', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5'	System	03 Oct 2020 19:36:12
User entered 'No interference with activity (1)'	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:49', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5' User entered 'None (0)'	System	03 Oct 2020 19:36:12
	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:35:51', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5' User entered 'None (0)'	System	03 Oct 2020 19:36:12
	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:36:01', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5' User entered 'None (0)'	System	03 Oct 2020 19:36:12
	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:36:05', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5' User entered 'No (N)'	System	03 Oct 2020 19:36:12
	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-03T14:36:10', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '62215f85-08e0-4408-82b5-946d1651ebe5' User entered '03 Oct 2020 14:36'	System	03 Oct 2020 19:36:12
	System	03 Oct 2020 19:36:12

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 4'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943'	System	04 Oct 2020 19:43:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered 'None (0)'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:39', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered 'None (0)'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:42', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered 'None (0)'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:43', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered 'None (0)'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:46', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered 'None (0)'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:49', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered 'No (N)'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-04T14:43:54', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a9aa9df2-4e01-40ce-94c9-b7f914f90943' User entered '04 Oct 2020 14:43'	System	04 Oct 2020 19:43:55
	System	04 Oct 2020 19:43:55

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 5'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'None (0)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:20', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'None (0)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:22', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'None (0)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:24', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'None (0)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'None (0)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'None (0)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:32', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered 'No (N)'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-05T18:28:34', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '222f624f-821e-478f-bb4d-6afd96b2fd4a' User entered '05 Oct 2020 18:28'	System	05 Oct 2020 23:28:38
	System	05 Oct 2020 23:28:38

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 6'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'None (0)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:31', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'None (0)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'None (0)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:36', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'None (0)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:39', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'None (0)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'None (0)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:45', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered 'No (N)'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T05:26:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '191a696c-a293-413f-be09-e0ea15185912' User entered '07 Oct 2020 05:26'	System	07 Oct 2020 10:26:50
	System	07 Oct 2020 10:26:50

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	01 Oct 2020 14:14:04
User entered 'Day 7'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:37', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered 'None (0)'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:39', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered 'None (0)'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:42', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered 'None (0)'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:44', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered 'None (0)'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:46', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered 'None (0)'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:48', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered 'None (0)'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

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 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8'	System	07 Oct 2020 21:22:00
User entered 'No (N)'	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-10-07T16:21:54', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'efe3a06c-bd04-4f9d-8aa2-e9837ca1fad8' User entered '07 Oct 2020 16:21'	System	07 Oct 2020 21:22:00
	System	07 Oct 2020 21:22:00

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 14:14:04

US3752402

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:49:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 14:14:04

US3752402

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:46:30

US3752402

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:46:30

US3752402

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:46:30

US3752402

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:46:30

US3752402

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Oct 2020 15:13:04

US3752402

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	16 Oct 2020 15:13:04

US3752402

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Oct 2020 15:13:12

US3752402

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '15 Oct 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Oct 2020 15:13:12

US3752402

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Oct 2020 15:13:12

US3752402

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:51:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Oct 2020 15:13:12

US3752402

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:52:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	16 Oct 2020 15:13:17

US3752402

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	16 Oct 2020 15:13:17

US3752402

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:52:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:15

US3752402

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:52:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:15

US3752402

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:52:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:15

US3752402

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:52:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:15

US3752402

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:53:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:19

US3752402

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	22 Oct 2020 14:57:19

US3752402

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:53:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:05:44

US3752402

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:53:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:05:44

US3752402

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:53:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:05:44

US3752402

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'VISIT3'	System	02 Nov 2020 18:05:44

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '08:12'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '30 Oct 2020 08:12'	System	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '69'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'bpm'	System	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '18'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'breaths/min'	System	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '126'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'mmHg'	System	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '74'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'mmHg'	System	02 Nov 2020 18:06:11

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35

US3752402

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35

US3752402

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:21

US3752402

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:21

US3752402

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User closed query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "Date is correct. Sample collected visit 3 day 57", however, this sample is not recorded in GCL. Please confirm the shipping information. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 11:56:26
Query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "Date is correct. Sample collected visit 3 day 57", however, this sample is not recorded in GCL. Please confirm the shipping information. ' answered with 'there are several that are marked received in Preclarus' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	18 Jan 2021 21:14:32
User opened query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "Date is correct. Sample collected visit 3 day 57", however, this sample is not recorded in GCL. Please confirm the shipping information. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 17:16:53
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 17:16:53
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' answered with 'Date is correct. Sample collected visit 3 day 57' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:24:40
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:34:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 18:06:38

US3752402

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:38

US3752402

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '08:19'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:38

US3752402

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered '30 Oct 2020 08:19'	System	02 Nov 2020 18:06:38

US3752402

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:06:48

US3752402

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	02 Nov 2020 18:06:48

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 64'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-04T08:40:54', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd82277e0-db16-483f-8f05-20fe8b7e70b7'	System	04 Nov 2020 14:41:11
User entered 'No (N)'	System	04 Nov 2020 14:41:11

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-04T08:40:59', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd82277e0-db16-483f-8f05-20fe8b7e70b7'	System	04 Nov 2020 14:41:11
User entered 'No (N)'	System	04 Nov 2020 14:41:11

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-04T08:41:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'd82277e0-db16-483f-8f05-20fe8b7e70b7' User entered '04 Nov 2020 08:41:04'	System	04 Nov 2020 14:41:11
	System	04 Nov 2020 14:41:11

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 71'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-11T06:47:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '2547644b-b183-46af-bcde-5e5dd13567be' User entered 'No (N)'	System	11 Nov 2020 12:47:22
	System	11 Nov 2020 12:47:22

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-11T06:47:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '2547644b-b183-46af-bcde-5e5dd13567be' User entered 'No (N)'	System	11 Nov 2020 12:47:22
	System	11 Nov 2020 12:47:22

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-11T06:47:20', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '2547644b-b183-46af-bcde-5e5dd13567be' User entered '11 Nov 2020 06:47:20'	System	11 Nov 2020 12:47:22
	System	11 Nov 2020 12:47:22

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:05:12
Data entry locked.	System	04 Sep 2020 15:45:53
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31
Data entry locked.	System	04 Sep 2020 15:45:53
User entered 'Day 78'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Please 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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Please 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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Please 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 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31
Data entry locked.	System	04 Sep 2020 15:45:53
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 15:45:53

US3752402

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:50:31
Data entry locked.	System	04 Sep 2020 15:45:53
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 15:45:53

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-23T16:04:45', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6f930a0-60d7-45dd-9734-74618c99fe80'	System	23 Nov 2020 22:04:57
User entered 'No (N)'	System	23 Nov 2020 22:04:57

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-23T16:04:52', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6f930a0-60d7-45dd-9734-74618c99fe80'	System	23 Nov 2020 22:04:57
User entered 'No (N)'	System	23 Nov 2020 22:04:57

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-23T16:04:55', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a6f930a0-60d7-45dd-9734-74618c99fe80' User entered '23 Nov 2020 16:04:55'	System	23 Nov 2020 22:04:57
	System	23 Nov 2020 22:04:57

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-29T08:03:03', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bee7e8be-c7e1-4d72-92e9-e43fea4066ca' User entered 'No (N)'	System	29 Nov 2020 14:03:20

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-29T08:03:12', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bee7e8be-c7e1-4d72-92e9-e43fea4066ca'	System	29 Nov 2020 14:03:20
User entered 'No (N)'	System	29 Nov 2020 14:03:20

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-11-29T08:03:17', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'bee7e8be-c7e1-4d72-92e9-e43fea4066ca' User entered '29 Nov 2020 08:03:17'	System	29 Nov 2020 14:03:20
	System	29 Nov 2020 14:03:20

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:45:18', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered 'Yes (Y)'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:45:32', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered 'No (N)'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:45:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered 'Yes (Y)'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered '1'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '0'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:46:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered '0'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:47:20', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:47:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered 'Yes (Y)'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:47:39', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135'	System	06 Dec 2020 13:48:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-06T07:47:49', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ccd896d5-999f-4a5a-93d3-8960a7965135' User entered '06 Dec 2020 07:47:49'	System	06 Dec 2020 13:48:00
	System	06 Dec 2020 13:48:00

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-13T05:09:51', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ae942a7b-0441-47b2-be3b-121640487264'	System	13 Dec 2020 11:10:50
User entered 'Yes (Y)'	System	13 Dec 2020 11:10:50

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-13T05:09:55', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ae942a7b-0441-47b2-be3b-121640487264' User entered 'No (N)'	System	13 Dec 2020 11:10:50
	System	13 Dec 2020 11:10:50

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-13T05:10:20', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ae942a7b-0441-47b2-be3b-121640487264' User entered 'No (N)'	System	13 Dec 2020 11:10:50
	System	13 Dec 2020 11:10:50

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-13T05:10:27', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ae942a7b-0441-47b2-be3b-121640487264'	System	13 Dec 2020 11:10:50
User entered 'Yes (Y)'	System	13 Dec 2020 11:10:50

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-13T05:10:36', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ae942a7b-0441-47b2-be3b-121640487264'	System	13 Dec 2020 11:10:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 11:10:50

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-13T05:10:42', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ae942a7b-0441-47b2-be3b-121640487264' User entered '13 Dec 2020 05:10:42'	System	13 Dec 2020 11:10:50
	System	13 Dec 2020 11:10:50

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-20T07:54:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'cdcb09d2-cd1f-4211-ab2a-682c4accfd0e' User entered 'No (N)'	System	20 Dec 2020 13:54:55
	System	20 Dec 2020 13:54:55

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-20T07:54:46', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'cdcb09d2-cd1f-4211-ab2a-682c4accfd0e' User entered 'No (N)'	System	20 Dec 2020 13:54:55
	System	20 Dec 2020 13:54:55

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-20T07:54:53', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'cdcb09d2-cd1f-4211-ab2a-682c4accfd0e' User entered '20 Dec 2020 07:54:53'	System	20 Dec 2020 13:54:55
	System	20 Dec 2020 13:54:55

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-27T06:01:04', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '52bdd2d7-b5f4-484b-9041-d1fc94733122'	System	27 Dec 2020 12:01:15
User entered 'No (N)'	System	27 Dec 2020 12:01:15

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-27T06:01:08', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '52bdd2d7-b5f4-484b-9041-d1fc94733122'	System	27 Dec 2020 12:01:15
User entered 'No (N)'	System	27 Dec 2020 12:01:15

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2020-12-27T06:01:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '52bdd2d7-b5f4-484b-9041-d1fc94733122' User entered '27 Dec 2020 06:01:13'	System	27 Dec 2020 12:01:15
	System	27 Dec 2020 12:01:15

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-03T05:48:28', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '34ec6fac-2426-4a8e-aa7f-13089f053129' User entered 'No (N)'	System	03 Jan 2021 11:48:37
	System	03 Jan 2021 11:48:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-03T05:48:30', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '34ec6fac-2426-4a8e-aa7f-13089f053129'	System	03 Jan 2021 11:48:37
User entered 'No (N)'	System	03 Jan 2021 11:48:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-03T05:48:35', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '34ec6fac-2426-4a8e-aa7f-13089f053129' User entered '03 Jan 2021 05:48:35'	System	03 Jan 2021 11:48:37
	System	03 Jan 2021 11:48:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-10T06:25:16', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '987d4092-020a-487c-88f4-a708f95313d1' User entered 'No (N)'	System	10 Jan 2021 12:25:37
	System	10 Jan 2021 12:25:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-10T06:25:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '987d4092-020a-487c-88f4-a708f95313d1' User entered 'No (N)'	System	10 Jan 2021 12:25:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-10T06:25:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '987d4092-020a-487c-88f4-a708f95313d1' User entered '10 Jan 2021 06:25:33'	System	10 Jan 2021 12:25:37
	System	10 Jan 2021 12:25:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-17T09:01:41', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fca0f8a7-c63f-4902-9446-3f268033577d' User entered 'No (N)'	System	17 Jan 2021 15:01:53

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-17T09:01:44', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fca0f8a7-c63f-4902-9446-3f268033577d' User entered 'No (N)'	System	17 Jan 2021 15:01:53

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-17T09:01:50', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'fca0f8a7-c63f-4902-9446-3f268033577d' User entered '17 Jan 2021 09:01:50'	System	17 Jan 2021 15:01:53
	System	17 Jan 2021 15:01:53

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-24T05:08:13', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '9659fa5f-5e0b-4f1c-b45c-9a79afbf2b95'	System	24 Jan 2021 11:08:35
User entered 'No (N)'	System	24 Jan 2021 11:08:35

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-24T05:08:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '9659fa5f-5e0b-4f1c-b45c-9a79afbf2b95'	System	24 Jan 2021 11:08:35
User entered 'No (N)'	System	24 Jan 2021 11:08:35

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-24T05:08:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '9659fa5f-5e0b-4f1c-b45c-9a79afbf2b95' User entered '24 Jan 2021 05:08:33'	System	24 Jan 2021 11:08:35

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-31T06:02:19', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '42308580-5f5b-4bf6-992a-4230729be323' User entered 'No (N)'	System	31 Jan 2021 12:02:33
	System	31 Jan 2021 12:02:33

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-31T06:02:23', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '42308580-5f5b-4bf6-992a-4230729be323'	System	31 Jan 2021 12:02:33
User entered 'No (N)'	System	31 Jan 2021 12:02:33

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-01-31T06:02:28', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '42308580-5f5b-4bf6-992a-4230729be323' User entered '31 Jan 2021 06:02:28'	System	31 Jan 2021 12:02:33
	System	31 Jan 2021 12:02:33

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-07T17:22:25', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4f86b94b-8ffc-455a-a856-f766ead9cb0c' User entered 'No (N)'	System	07 Feb 2021 23:23:10
	System	07 Feb 2021 23:23:10

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-07T17:22:33', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4f86b94b-8ffc-455a-a856-f766ead9cb0c' User entered 'No (N)'	System	07 Feb 2021 23:23:10

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-07T17:22:36', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '4f86b94b-8ffc-455a-a856-f766ead9cb0c' User entered '07 Feb 2021 17:22:36'	System	07 Feb 2021 23:23:10
	System	07 Feb 2021 23:23:10

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-14T13:03:14', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '057c2645-f4b7-4e8a-a8ea-3efaeb7a36f2' User entered 'Yes (Y)'	System	14 Feb 2021 19:04:19

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-14T13:03:19', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '057c2645-f4b7-4e8a-a8ea-3efaeb7a36f2' User entered 'No (N)'	System	14 Feb 2021 19:04:19

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-14T13:03:29', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '057c2645-f4b7-4e8a-a8ea-3efaeb7a36f2' User entered 'No (N)'	System	14 Feb 2021 19:04:19

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-14T13:03:38', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '057c2645-f4b7-4e8a-a8ea-3efaeb7a36f2' User entered 'Yes (Y)'	System	14 Feb 2021 19:04:19

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-14T13:03:57', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '057c2645-f4b7-4e8a-a8ea-3efaeb7a36f2'	System	14 Feb 2021 19:04:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 19:04:19

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-14T13:04:07', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '057c2645-f4b7-4e8a-a8ea-3efaeb7a36f2' User entered '14 Feb 2021 13:04:07'	System	14 Feb 2021 19:04:19

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-24T09:51:32-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ec4f57b2-d403-4dc5-ba51-eb6e298819af'	System	24 Feb 2021 15:52:52
User entered 'Yes (Y)'	System	24 Feb 2021 15:52:52

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-24T09:51:36-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ec4f57b2-d403-4dc5-ba51-eb6e298819af' User entered 'No (N)'	System	24 Feb 2021 15:52:52

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-24T09:52:20-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ec4f57b2-d403-4dc5-ba51-eb6e298819af' User entered 'No (N)'	System	24 Feb 2021 15:52:52
	System	24 Feb 2021 15:52:52

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-24T09:52:28-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ec4f57b2-d403-4dc5-ba51-eb6e298819af' User entered 'Yes (Y)'	System	24 Feb 2021 15:52:52

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-24T09:52:33-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ec4f57b2-d403-4dc5-ba51-eb6e298819af'	System	24 Feb 2021 15:52:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Feb 2021 15:52:52

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-24T09:52:39-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'ec4f57b2-d403-4dc5-ba51-eb6e298819af' User entered '24 Feb 2021 15:52:39'	System	24 Feb 2021 15:52:52
	System	24 Feb 2021 15:52:52

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-01T15:04:21-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94a05b81-ab37-4d8c-95b4-3c5d1cc26bfc' User entered 'Yes (Y)'	System	01 Mar 2021 21:05:02
	System	01 Mar 2021 21:05:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-01T15:04:30-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94a05b81-ab37-4d8c-95b4-3c5d1cc26bfc' User entered 'No (N)'	System	01 Mar 2021 21:05:02
	System	01 Mar 2021 21:05:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-01T15:04:36-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94a05b81-ab37-4d8c-95b4-3c5d1cc26bfc' User entered 'No (N)'	System	01 Mar 2021 21:05:02
	System	01 Mar 2021 21:05:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-01T15:04:41-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94a05b81-ab37-4d8c-95b4-3c5d1cc26bfc' User entered 'Yes (Y)'	System	01 Mar 2021 21:05:02
	System	01 Mar 2021 21:05:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-01T15:04:45-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94a05b81-ab37-4d8c-95b4-3c5d1cc26bfc'	System	01 Mar 2021 21:05:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Mar 2021 21:05:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-01T15:04:50-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '94a05b81-ab37-4d8c-95b4-3c5d1cc26bfc' User entered '01 Mar 2021 15:04:50'	System	01 Mar 2021 21:05:02
	System	01 Mar 2021 21:05:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-07T18:32:36-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '752f2f5b-cf33-44cb-a735-7a0cfc1e9795'	System	14 Mar 2021 18:35:37
User entered 'Yes (Y)'	System	14 Mar 2021 18:35:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-07T18:32:40-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '752f2f5b-cf33-44cb-a735-7a0cfc1e9795'	System	14 Mar 2021 18:35:37
User entered 'No (N)'	System	14 Mar 2021 18:35:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-07T18:32:46-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '752f2f5b-cf33-44cb-a735-7a0cfc1e9795'	System	14 Mar 2021 18:35:37
User entered 'No (N)'	System	14 Mar 2021 18:35:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-07T18:32:51-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '752f2f5b-cf33-44cb-a735-7a0cfc1e9795'	System	14 Mar 2021 18:35:37
User entered 'Yes (Y)'	System	14 Mar 2021 18:35:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-07T18:32:55-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '752f2f5b-cf33-44cb-a735-7a0cfc1e9795'	System	14 Mar 2021 18:35:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Mar 2021 18:35:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-07T18:33:03-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '752f2f5b-cf33-44cb-a735-7a0cfc1e9795'	System	14 Mar 2021 18:35:37
User entered '07 Mar 2021 18:33:03'	System	14 Mar 2021 18:35:37

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-14T13:35:42-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e98c45f3-3af5-4711-8d63-d1bee4e4be5f'	System	14 Mar 2021 18:35:59
User entered 'No (N)'	System	14 Mar 2021 18:35:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-14T13:35:47-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e98c45f3-3af5-4711-8d63-d1bee4e4be5f'	System	14 Mar 2021 18:35:59
User entered 'No (N)'	System	14 Mar 2021 18:35:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-14T13:35:55-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e98c45f3-3af5-4711-8d63-d1bee4e4be5f' User entered '14 Mar 2021 13:35:55'	System	14 Mar 2021 18:35:59
	System	14 Mar 2021 18:35:59

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-24T06:35:09-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b97d1109-0921-4167-8180-b86b2c42a82f' User entered 'No (N)'	System	24 Mar 2021 11:35:24
	System	24 Mar 2021 11:35:24

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-24T06:35:14-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b97d1109-0921-4167-8180-b86b2c42a82f'	System	24 Mar 2021 11:35:24
User entered 'No (N)'	System	24 Mar 2021 11:35:24

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-24T06:35:21-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'b97d1109-0921-4167-8180-b86b2c42a82f' User entered '24 Mar 2021 06:35:21'	System	24 Mar 2021 11:35:24
	System	24 Mar 2021 11:35:24

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-31T17:59:55-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8c3fd6ea-d6e0-4d9b-97ab-8f18ac4ce3fd'	System	31 Mar 2021 23:00:08
User entered 'No (N)'	System	31 Mar 2021 23:00:08

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-31T17:59:59-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8c3fd6ea-d6e0-4d9b-97ab-8f18ac4ce3fd'	System	31 Mar 2021 23:00:08
User entered 'No (N)'	System	31 Mar 2021 23:00:08

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-03-31T18:00:02-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '8c3fd6ea-d6e0-4d9b-97ab-8f18ac4ce3fd' User entered '31 Mar 2021 18:00:02'	System	31 Mar 2021 23:00:08
	System	31 Mar 2021 23:00:08

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-05T08:07:34-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9bf4e9-d915-45cd-9eb4-4810c3327b4b' User entered 'No (N)'	System	05 Apr 2021 13:07:44
	System	05 Apr 2021 13:07:44

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-05T08:07:39-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9bf4e9-d915-45cd-9eb4-4810c3327b4b' User entered 'No (N)'	System	05 Apr 2021 13:07:44
	System	05 Apr 2021 13:07:44

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-05T08:07:42-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '0f9bf4e9-d915-45cd-9eb4-4810c3327b4b'	System	05 Apr 2021 13:07:44
User entered '05 Apr 2021 08:07:42'	System	05 Apr 2021 13:07:44

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-13T06:20:39-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '001fd716-4486-4ee3-bdcf-e9c286d97d4b' User entered 'No (N)'	System	13 Apr 2021 11:20:55
	System	13 Apr 2021 11:20:55

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-13T06:20:44-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '001fd716-4486-4ee3-bdcf-e9c286d97d4b' User entered 'No (N)'	System	13 Apr 2021 11:20:55

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-13T06:20:48-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '001fd716-4486-4ee3-bdcf-e9c286d97d4b'	System	13 Apr 2021 11:20:55
User entered '13 Apr 2021 06:20:48'	System	13 Apr 2021 11:20:55

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-18T05:46:02-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a76b2561-5859-4dd1-8617-721275a8464b'	System	18 Apr 2021 10:46:16
User entered 'No (N)'	System	18 Apr 2021 10:46:16

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-18T05:46:06-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a76b2561-5859-4dd1-8617-721275a8464b'	System	18 Apr 2021 10:46:16
User entered 'No (N)'	System	18 Apr 2021 10:46:16

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-18T05:46:10-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'a76b2561-5859-4dd1-8617-721275a8464b'	System	18 Apr 2021 10:46:16
User entered '18 Apr 2021 05:46:10'	System	18 Apr 2021 10:46:16

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-27T12:00:47-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e584b9d2-3f72-49b6-867f-b6ad5f7a74dd'	System	29 Apr 2021 04:51:42
User entered 'No (N)'	System	29 Apr 2021 04:51:42

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-27T12:00:51-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e584b9d2-3f72-49b6-867f-b6ad5f7a74dd'	System	29 Apr 2021 04:51:42
User entered 'No (N)'	System	29 Apr 2021 04:51:42

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-04-27T12:00:55-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'e584b9d2-3f72-49b6-867f-b6ad5f7a74dd'	System	29 Apr 2021 04:51:42
User entered '27 Apr 2021 12:00:55'	System	29 Apr 2021 04:51:42

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-05-02T11:46:54-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '5ea2a106-b6df-4d1e-9ff9-3b27a0def205'	System	02 May 2021 16:47:02
User entered 'No (N)'	System	02 May 2021 16:47:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Have you been exposed to someone with 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 (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-05-02T11:46:56-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '5ea2a106-b6df-4d1e-9ff9-3b27a0def205'	System	02 May 2021 16:47:02
User entered 'No (N)'	System	02 May 2021 16:47:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-05-02T11:47:00-05:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: '5ea2a106-b6df-4d1e-9ff9-3b27a0def205'	System	02 May 2021 16:47:02
User entered '02 May 2021 11:47:00'	System	02 May 2021 16:47:02

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 03:50:31

US3752402

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:49:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:50:31
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 03:50:31

US3752402

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:49:01

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 13:54:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-27T09:19:27-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dd86a2fb-48e0-495f-84f1-1bb119a8add1'	System	27 Feb 2021 15:19:37
User entered 'No (N)'	System	27 Feb 2021 15:19:37

US3752402

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:49:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:54:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EF211379-8DE2-4C30-8C2B-2635A5AF53B4)', Time: '2021-02-27T09:19:32-06:00', User OID: 'PatientReportedOutcome (US3752402)', ODM File OID: 'dd86a2fb-48e0-495f-84f1-1bb119a8add1' User entered '27 Feb 2021 15:19:32'	System	27 Feb 2021 15:19:37
	System	27 Feb 2021 15:19:37

US3752402

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:55:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:09

US3752402

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:55:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:09

US3752402

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:55:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:09

US3752402

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:55:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:57
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:09

US3752402

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:58:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:02:13

US3752402

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:12:35
User entered 'I'	System	23 Nov 2020 16:02:13

US3752402

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:58:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4)	30 Dec 2020 23:06:55
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:58:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '30 Dec 2020'	(b) (4)	
	Amanda Horn (b) (4)	30 Dec 2020 23:06:55
	(b) (4)	

US3752402

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:58:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4)	30 Dec 2020 23:06:55

US3752402

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:58:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	Amanda Horn (b) (4)	30 Dec 2020 23:06:55

US3752402

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:00:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	Amanda Horn (b) (4)	30 Dec 2020 23:07:02

US3752402

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User entered 'I'	System	30 Dec 2020 23:07:02

US3752402

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:00:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4)	29 Jan 2021 15:14:18
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User closed query 'please verify if D179 call completed and provide source-due 3Mar' (Site from CRA).	(b) (4), (b) (6)	28 Mar 2021 03:48:42
Query 'please verify if D179 call completed and provide source-due 3Mar' answered with 'Added. ' (Site from CRA).	Haylee Rowe (b) (4)	10 Mar 2021 21:54:04
User opened query 'please verify if D179 call completed and provide source-due 3Mar' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 22:02:54
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:00:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '27 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	29 Jan 2021 15:14:18
	(b) (4)	

US3752402

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:00:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4)	29 Jan 2021 15:14:18

US3752402

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:00:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	Amanda Horn (b) (4)	29 Jan 2021 15:14:18

US3752402

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:00:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4)	29 Jan 2021 15:14:22
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User entered 'I'	System	29 Jan 2021 15:14:22

US3752402

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:42:11
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	10 Mar 2021 21:54:17
	(b) (4)	

US3752402

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:42:11
User entered '25 Feb 2021'	Haylee Rowe (b) (4)	10 Mar 2021 21:54:17
	(b) (4)	

US3752402

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:42:11
User entered 'Contact Made (CONTACT MADE)'	Haylee Rowe (b) (4)	10 Mar 2021 21:54:17
	(b) (4)	

US3752402

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:42:11
User entered empty.	Haylee Rowe (b) (4)	10 Mar 2021 21:54:17
	(b) (4)	

US3752402

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:43:06
User entered 'Yes (Y)'	Haylee Rowe (b) (4)	10 Mar 2021 21:54:21
	(b) (4)	

US3752402

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:45:52
User entered 'I'	System	10 Mar 2021 21:54:21

US3752402

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:45
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:49:48

US3752402

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:45
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:49:48

US3752402

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:45
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:49:48

US3752402

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered 'VISIT4'	System	05 Apr 2021 16:49:48

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '09:10'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered '5 Apr 2021 09:10'	System	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '83'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered 'bpm'	System	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered 'breaths/min'	System	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '128'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered 'mmHg'	System	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:55:32
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '78'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered 'mmHg'	System	05 Apr 2021 16:50:30

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53

US3752402

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:49:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53

US3752402

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:56:22
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:41

US3752402

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:49:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:56:22
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:41

US3752402

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:02:47
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:57

US3752402

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:02:47
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:57

US3752402

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:02:47
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '09:19'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:50:57

US3752402

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered '5 Apr 2021 09:19'	System	05 Apr 2021 16:50:57

US3752402

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:02:53
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:51:15

US3752402

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:53
User entered 'I'	System	05 Apr 2021 16:51:15

US3752402

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	29 Apr 2021 22:28:59
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	29 Apr 2021 15:40:28
	(b) (4)	

US3752402

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	29 Apr 2021 22:28:59
	(b) (4)	
User entered '29 Apr 2021'	Timothy Campbell (b) (4)	29 Apr 2021 15:40:28
	(b) (4)	

US3752402

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	29 Apr 2021 22:28:59
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	29 Apr 2021 15:40:28
	(b) (4)	

US3752402

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:49:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	29 Apr 2021 22:28:59
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	29 Apr 2021 15:40:28
	(b) (4)	

US3752402

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	29 Apr 2021 22:28:59
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	29 Apr 2021 15:40:34
	(b) (4)	

US3752402

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:49:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 15:40:34

US3752402

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:28

US3752402

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:28

US3752402

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:28

US3752402

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

Form: Visit Date

Generated On: 10 Jun 2021 09:49:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 20:52:28

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 21:47:34
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 16:53:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	22 Apr 2021 15:36:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:20:58

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 21:47:34
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 12:04:01
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 16:53:49
	(b) (4)	
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).	Lauren Evans (b) (4)	22 Apr 2021 15:36:54
User entered 'Amendment 6 or later (Amendment 6 or later)'	Lauren Evans (b) (4)	22 Apr 2021 15:36:36
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 06:36:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:20:58

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 04:12:44
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 04:12:44
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:04:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
User entered empty.	System	19 Jan 2021 20:52:49

US3752402

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

Form: Unblinding

Generated On: 10 Jun 2021 09:49:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
User entered empty.	System	19 Jan 2021 20:52:49

US3752402

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:53:14

US3752402

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:53:14

US3752402

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '14:09'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:53:14

US3752402

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:49:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
User entered '19 Jan 2021 14:09'	System	19 Jan 2021 20:53:14

US3752402

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:53:25

US3752402

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:53:25

US3752402

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:05:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '14:07'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:53:25

US3752402

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:49:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:11
User entered '19 Jan 2021 14:07'	System	19 Jan 2021 20:53:25

US3752402

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:49:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:21:05
User closed query 'Per DM CLR: Per Day 96 and 103 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 04:09:57
Query 'Per DM CLR: Per Day 96 and 103 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Reports did see PCP but there were no AEs to report' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	18 Mar 2021 15:00:46
User opened query 'Per DM CLR: Per Day 96 and 103 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:58:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:11:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:51:48

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 20:13:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 20:13:24
Data point term sent to Coder	System	05 Nov 2020 20:12:43
User entered 'Headache'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '07 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
User entered empty.	System	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '14 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
User entered empty.	System	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Related (RELATED)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Related (RELATED)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
User entered '0'	System	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12
User entered '0'	System	05 Nov 2020 20:12:41

US3752402

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:49:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:16:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'USA-US113-2021-mRNA-1273-P301000006'	System	26 Feb 2021 18:04:45
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:04:45
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:18:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:18:20
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:16:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:16:42
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:16:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 17:16:22

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas non-Hodgkin's B-cell, HLT: B-cell lymphomas NEC, PT: High-grade B-cell lymphoma, LLT: High-grade B-cell lymphoma - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 11:20:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 11:20:45
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 17:55:36
User entered 'HIGH GRADE B-CELL LYMPHOMA' reason for change: Data Entry Error	Amanda Horn (b) (4)	01 Mar 2021 17:55:09
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 23:11:09
User entered 'LEUKEMIA-LYMPHOMA, T-CELL, ACUTE, HTLV I'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Yes (Y)'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '5 Feb 2021'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered empty.	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Yes (Y)'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:06:03
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'END DATE COINCIDES WITH DATE OF DIAGNOSIS OF CONDITION AS ONE THAT IS CHRONIC/RECURRENT' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:10:11
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:09:57
Signature has been broken.	Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:09:57
User entered '26 Feb 2021' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:09:57
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:37:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Grade 4 (Grade 4)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '0'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'I'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
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)	01 Mar 2021 16:07:59
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 'HOSPITAL ADMISSION DATE PROVIDED, NOT DISCHARGED YET' (Site from System).	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Feb 2021 23:10:12
User entered 'I'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 15:06:07
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'END DATE COINCIDES WITH DATE OF DIAGNOSIS OF CONDITION AS ONE THAT IS CHRONIC/RECURRENT' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:41:05
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:33:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '25 Feb 2021'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User closed query 'please verify a 26Feb21 per hosp discharge summary.' (Site from CRA).	(b) (4), (b) (6)	28 Mar 2021 03:47:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:00:39
Query 'please verify a 26Feb21 per hosp discharge summary.' answered with 'Updated. ' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:46:38
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'Discharge date updated. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:46:31
DataPoint Un-verified.	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:46:18
User entered '26 Feb 2021' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User opened query 'please verify a 26Feb21 per hosp discharge summary.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 22:12:58
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 07:20:56
User entered empty.	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '0'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

US3752402

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '0'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '0'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

None

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '0'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered 'I'	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:31:35
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'biopsy is diagnostic' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 20:55:37
User entered '1' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 20:55:26
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 20:55:10
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 20:55:10
User entered '0' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	17 Mar 2021 20:55:10
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 20:25:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered '1'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
Signature has been broken.	(b) (4) Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4) Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:00:43
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'Updated to recovering/resolving. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:52:17
DataPoint Un-verified.	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:46:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Mar 2021 21:46:18
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 07:21:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:12

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User entered 'NEW BASELINE ESTABLISHED WITH DIAGNOSIS OF LYMPHOMA. SUBJECT WILL BE GOING THROUGH 6 ROUNDS OF CHEMOTHERAPY.' reason for change: Data Entry Error	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:20:14
User entered empty.	Amanda Horn (b) (4)	25 Feb 2021 23:10:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:17:38
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
Signature has been broken.	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User entered 'BIOPSY RESULTS: HIGH GRADE B-CELL LYMPHOMA.' reason for change: Data Entry Error	Amanda Horn (b) (4)	31 Mar 2021 16:09:57
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:00:58
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 15:00:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'No results available at this time ' (Site from Safety).	Haylee Rowe (b) (4)	10 Mar 2021 21:51:35
	(b) (4)	
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'No COVID-19 testing was obtained. ' (Site from Safety).	Haylee Rowe (b) (4)	10 Mar 2021 21:51:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:20:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 07:20:24
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 07:19:53
User entered 'BIOPSY RESULTS: HIGH GRADE B-CELL LYMPHOMA' reason for change: Data Entry Error	Amanda Horn (b) (4)	01 Mar 2021 18:03:00
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 14:57:42
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 14:57:42
User entered 'SUBJECT IS CURRENTLY ADMITTED AND SCHEDULED FOR BIOPSY TODAY.' reason for change: Data Entry Error	Amanda Horn (b) (4)	26 Feb 2021 14:57:42
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 23:10:12
User entered empty.	Amanda Horn (b) (4)	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 23:10:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:49:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 23:10:12

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:14
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:44:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 04:19:19
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'ibuprofen was the only thing listed after the safety follow up call' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	02 Feb 2021 15:55:37
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 02:42:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:51:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 16:53:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:53:55
Data point term sent to Coder	System	08 Sep 2020 16:53:02
User entered 'Atorvastatin'	(b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '10'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 16:52:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 16:54:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:54:55
Data point term sent to Coder	System	08 Sep 2020 16:54:04
User entered 'Sumatriptan'	(b) (4), (b) (6)	08 Sep 2020 16:53:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Migraine headaches'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '100'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:53:55

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 16:55:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:55:53
Data point term sent to Coder	System	08 Sep 2020 16:55:05
User entered 'Melatonin'	(b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '12'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'un Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 16:54:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 00:07:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:07:59
Data point term sent to Coder	System	08 Oct 2020 19:47:58
User entered 'Ibuprofen'	(b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER, CHILLS are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 12:57:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER, CHILLS are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' answered with 'FEVER and CHILLS are reported in e-diary and did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 16:10:13

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER, CHILLS are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:17:22
User entered 'fever, chills'	(b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '200'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '3 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:56
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
User entered '2'	System	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
User entered '1'	System	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:21:59
User entered '804 (804)'	System	08 Oct 2020 19:47:50

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	05 Nov 2020 06:58:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 06:58:55
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 18:08:36
User entered 'Seasonal influenza vaccine'	(b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Prophylaxis for seasonal influenza'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0.5'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	23 Nov 2020 22:18:53
User entered '17 Oct 2020'	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Nov 2020 22:18:53
	(b) (4)	
User entered '17 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
User entered empty.	System	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
User entered empty.	System	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:02
User entered empty.	System	02 Nov 2020 18:08:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Mar 2021 22:18:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:18:52
Data point term sent to Coder	System	02 Mar 2021 18:30:10
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:30:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:26:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:26:01
Data point term sent to Coder	System	25 Feb 2021 23:15:16
User entered 'DEXAMETHASONE'	Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'HIGH-GRADE B-CELL	(b) (4)	
LYMPHOMA' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Mar 2021 18:30:08
User entered 'LEUKEMIA-LYMPHOMA, T-CELL,	(b) (4)	
ACUTE, HTLV I ASSOCIATED'	Amanda Horn (b) (4)	25 Feb 2021 23:14:41
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '10'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'mg (mg)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'once (ONCE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	25 Feb 2021 23:14:41
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	25 Feb 2021 23:14:41
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '25 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '25 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
User entered empty.	System	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
User entered empty.	System	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:05
User entered empty.	System	25 Feb 2021 23:14:41

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 18:36:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:36:44
Data point term sent to Coder	System	02 Mar 2021 18:36:19
User entered 'HYDROCODONE/ACETAMINOPHEN'	Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'HIGH-GRADE B-CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '7.5/325'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'mg (mg)'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	02 Mar 2021 18:35:20
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'Q6H PRN'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'Oral (ORAL)'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '23 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
Signature has been broken.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:47:26
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:47:26
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:41:03
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
Signature has been broken.	Amanda Horn (b) (4)	09 Mar 2021 18:47:26
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4) Amanda Horn (b) (4)	09 Mar 2021 18:47:26
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4) Amanda Horn (b) (4)	02 Mar 2021 18:35:20
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
User entered empty.	System	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
User entered empty.	System	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:09
User entered empty.	System	02 Mar 2021 18:35:20

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
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: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:50:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:50:39
Data point term sent to Coder	System	09 Mar 2021 18:49:34
Data point term sent to Coder	System	09 Mar 2021 18:49:34
User entered 'OMNIPAQUE'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 18:49:18
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '75'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4)	09 Mar 2021 18:49:18
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 18:49:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 18:49:33
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:33
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 18:49:18
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 18:49:18
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User entered empty.	System	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User entered empty.	System	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:21
User entered empty.	System	09 Mar 2021 18:49:18

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:53:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:53:38
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:51:38
User entered 'OXYCODONE/ACETAMINOPHEN'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '5/325'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Q8H PRN'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4)	09 Mar 2021 18:50:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 18:50:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4)	11 Mar 2021 16:40:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 16:40:50
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:54:39
User entered 'DOXYCYCLINE'	Amanda Horn (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '100'	Amanda Horn (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '23 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:53:53
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User entered '1'	System	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User entered '1'	System	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:24
User entered '804 (804)'	System	09 Mar 2021 18:53:53

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
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 17:37:02
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 17:37:02
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
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)	10 Mar 2021 10:57:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 10:57:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:55:41
User entered '0.9% NACL'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ROUTINE HYDRATION'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '100'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 18:54:58
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'PER HOUR'	Amanda Horn (b) (4)	09 Mar 2021 18:54:58
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User entered empty.	System	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User entered empty.	System	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:25
User entered empty.	System	09 Mar 2021 18:54:58

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:56:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:56:40
Data point term sent to Coder	System	09 Mar 2021 18:55:41
User entered 'ACETAMINOPHEN'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '1000'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4)	09 Mar 2021 18:55:35
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:55:35
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:55:35
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User entered empty.	System	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User entered empty.	System	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:31
User entered empty.	System	09 Mar 2021 18:55:35

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:57:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:57:39
Data point term sent to Coder	System	09 Mar 2021 18:56:42
User entered 'LACTATED RINGERS'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ROUTINE HYDRATION'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '1000'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'PER HOUR'	Amanda Horn (b) (4)	09 Mar 2021 18:56:37
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:56:37
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User entered empty.	System	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User entered empty.	System	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:34
User entered empty.	System	09 Mar 2021 18:56:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:26:39
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:57:45
User entered 'ROCEPHIN IN NACL 0.9%'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'l'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'g (g)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User entered empty.	System	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User entered empty.	System	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:36
User entered empty.	System	09 Mar 2021 18:57:29

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Mar 2021 11:32:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:32:50
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:58:45
User entered 'CELECOXIB'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '200'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4)	09 Mar 2021 18:58:03
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	09 Mar 2021 18:58:03
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User entered empty.	System	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User entered empty.	System	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:40
User entered empty.	System	09 Mar 2021 18:58:03

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
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: ELECTROLYTES NOS, PRODUCTSYNONYM: ELECTROLYTE SOLUTIONS [ELECTROLYTES NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:26:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:26:03
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:59:46
User entered 'ELECTROLYTE-A'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ROUTINE PRE-PROCEDURE MEDICATION'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'other (OTHER)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'PER HOUR'	Amanda Horn (b) (4)	09 Mar 2021 18:58:54
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:58:54
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:58:54
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User entered empty.	System	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User entered empty.	System	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:46
User entered empty.	System	09 Mar 2021 18:58:54

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 11:35:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:35:44
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 18:59:46
User entered 'FAMOTIDINE'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ROUTINE PRE-PROCEDURE MEDICATION'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '20'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User closed query 'Per CDM CR: 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)	15 Apr 2021 14:32:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:20:40
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
Query 'Per CDM CR: 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).	Jamie Pettus (b) (4)	26 Mar 2021 13:11:48
DataPoint Un-verified.	Jamie Pettus (b) (4)	26 Mar 2021 13:11:33
Signature has been broken.	Jamie Pettus (b) (4)	26 Mar 2021 13:11:33
User entered 'mg (mg)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	26 Mar 2021 13:11:33
User opened query 'Per CDM CR: 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)	26 Mar 2021 12:58:36
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ug (ug)'	Amanda Horn (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 18:59:33
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User entered empty.	System	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User entered empty.	System	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:48
User entered empty.	System	09 Mar 2021 18:59:33

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:50:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:50:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:00:47
User entered 'MIDAZOLAM'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ROUTINE PREPROCEDURE MEDICATION'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '2'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:00:37
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 19:00:37
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User entered empty.	System	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User entered empty.	System	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:53
User entered empty.	System	09 Mar 2021 19:00:37

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
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)	16 Mar 2021 12:33:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:33:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:01:48
User entered 'MORPHINE'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '2'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 19:01:21
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Q4H PRN'	Amanda Horn (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	09 Mar 2021 19:01:21
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:01:21
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4)	09 Mar 2021 19:01:21
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User entered empty.	System	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User entered empty.	System	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User entered empty.	System	09 Mar 2021 19:01:21

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:25:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:25:50
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:02:50
User entered 'SODIUM CHLORIDE'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'ROUTINE IV FLUSH'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '3'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'twice daily (BID)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User entered '2'	System	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User entered '1'	System	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:02
User entered '804 (804)'	System	09 Mar 2021 19:02:09

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 07:16:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:16:43
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:02:50
User entered 'TRAMADOL'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '100'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User entered empty.	System	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User entered empty.	System	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:06
User entered empty.	System	09 Mar 2021 19:02:48

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;EPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Mar 2021 11:34:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:34:50
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:04:51
User entered 'BUPIVACAINE-EPINEPHRINE 0.5%'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'PROCEDURE ANESTHESIA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '30'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mL (mL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Intralesional (INTRALESIONAL)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn	(b) (4)
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:04:30
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User entered empty.	System	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User entered empty.	System	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:14
User entered empty.	System	09 Mar 2021 19:04:30

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
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.	Coder Import (b) (4) (b) (4)	09 Mar 2021 19:06:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 19:06:40
Data point term sent to Coder	System	09 Mar 2021 19:05:52
User entered 'ONDANSETRON HCL'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'POSTPROCEDURE PREVENTION OF NAUSEA, VOMITING'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '4'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 19:05:47
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Q6H PRN'	Amanda Horn (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn	(b) (4)
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User entered empty.	System	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User entered empty.	System	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:17
User entered empty.	System	09 Mar 2021 19:05:47

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
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)	16 Mar 2021 12:33:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:33:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:06:54
User entered 'MORPHINE'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'HIGH GRADE B CELL LYMPHOMA'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '6'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once (ONCE)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'Intravenous (INTRAVENOUS)'	Amanda Horn (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:06:22
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered '25 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User entered empty.	System	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User entered empty.	System	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:21
User entered empty.	System	09 Mar 2021 19:06:22

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:26:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:26:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:07:55
User entered 'PREDNISOLONE ACETATE 1%'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'POSTPROCEDURE INFLAMMATION PREVENTION'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'I'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'GTT'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'four times daily (QID)'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'OPHTHALMIC'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '23 Dec 2020'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4)	09 Mar 2021 19:07:34
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 19:07:34

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC SODIUM, PRODUCTSYNONYM: PROLENSA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 08:07:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 08:07:42
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder	System	09 Mar 2021 19:08:55
User entered 'PROLENSA [BROMFENAC OPHTHALMIC SOLUTION 0.07%]'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'POSTPROCEDURE INFLAMMATION'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'I'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'GTT'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'once daily (QD)'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Other (OTHER)'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'OPHTHALMIC'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '23 Dec 2020'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Yes (Y)'	Amanda Horn (b) (4)	09 Mar 2021 19:08:46
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 19:08:46

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:23:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:23:44
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:19:25
Data point term sent to Coder User entered 'MOXIFLOXACIN'	System Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:57 09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'PREVENTION OF POSTPROCEDURE INFECTION'	Amanda Horn (b) (4)	09 Mar 2021 19:12:05
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'l'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Other (OTHER)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	09 Mar 2021 22:19:25
User entered 'GTT'	Amanda Horn (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'twice daily (BID)'	Amanda Horn (b) (4)	09 Mar 2021 19:12:05
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'Other (OTHER)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'OPHTHALMIC'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '23 Dec 2020'	Amanda Horn	09 Mar 2021 19:12:05
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '0'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:14:56
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered '30 Dec 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:14:56
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:25
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User entered '2'	System	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User entered '1'	System	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:25
User entered '804 (804)'	System	09 Mar 2021 19:12:05

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 07:05:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 07:05:28
Data point term sent to Coder	System	31 Mar 2021 16:12:46
User entered 'PREDNISONE'	Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'No (N)'	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'HIGH GRADE B-CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered '20'	(b) (4) Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'mg (mg)'	(b) (4) Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered empty.	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'ONCE DAILY X5 DAYS FOLLOWING ROUND OF CHEMOTHERAPY'	(b) (4) Amanda Horn (b) (4) (b) (4)	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'Oral (ORAL)'	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered empty.	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered '11 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	31 Mar 2021 16:12:01
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered '0'	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered empty.	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'No (N)'	(b) (4)	31 Mar 2021 16:12:01
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:12:01

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:13:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:13:35
Data point term sent to Coder	System	05 Apr 2021 16:49:01
Data point term sent to Coder	System	05 Apr 2021 16:42:52
User entered 'ODANSETRON'	(b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'NAUSEA AND VOMITING POST CHEMOTHERAPY' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:42
User entered 'NAUSEA AND VOMITING'	(b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '4'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:42:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 16:49:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 16:49:21
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Apr 2021 16:48:01 05 Apr 2021 16:47:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 16:45:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 16:45:30
Data point term sent to Coder User entered 'TRAZODONE'	System (b) (4), (b) (6)	05 Apr 2021 16:43:55 05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'INSOMNIA' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:47:53
User entered 'SLEEP'	(b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '50'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:43:00

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:03:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:03:37
Data point term sent to Coder	System	05 Apr 2021 16:49:01
Data point term sent to Coder	System	05 Apr 2021 16:44:55
User entered 'PROMETHAZINE'	(b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'NAUSEA AND VOMITING POST CHEMOTHERAPY' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:48:24
User entered 'NAUSEA AND VOMITING'	(b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '25'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:44:19

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 10:25:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:25:57
Data point term sent to Coder	System	05 Apr 2021 16:47:00
User entered 'ALLOPURINOL'	(b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'HIGH GRADE B CELL LYMPHOMA'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '300'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:46:40

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSTIMULANTS, ATC: IMMUNOSTIMULANTS, ATC: COLONY STIMULATING FACTORS, PRODUCT: PEGFILGRASTIM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 10:12:45
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 10:12:45
Data point term sent to Coder	System	05 Apr 2021 17:56:27
User entered 'PEGFILGRASTIM'	Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'HIGH GRADE B CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:26
User closed query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:18:57
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 15:05:45
Query 'please provide source' answered with 'data updated per query' (Site from CRA).	(b) (4)	08 Apr 2021 14:09:36
Signature has been broken.	Lauren Evans (b) (4)	08 Apr 2021 14:09:14
User entered '1' reason for change: Data Entry Error	Lauren Evans (b) (4)	08 Apr 2021 14:09:14
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User opened query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:46:45
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '6'	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:24
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 15:05:45
DataPoint Un-verified.	(b) (4)	08 Apr 2021 14:09:14
Signature has been broken.	Lauren Evans (b) (4)	08 Apr 2021 14:09:14
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lauren Evans (b) (4)	08 Apr 2021 14:09:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:19:28
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 15:05:45
DataPoint Un-verified.	(b) (4)	08 Apr 2021 14:09:14
Signature has been broken.	Lauren Evans (b) (4)	08 Apr 2021 14:09:14
User entered 'Injection' reason for change: Data Entry Error	Lauren Evans (b) (4)	08 Apr 2021 14:09:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'ONCE EVERY 3 WEEKS'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '11 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 17:55:31
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:55:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 17:55:31
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:55:31

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS, ATC: VINCA ALKALOIDS AND ANALOGUES, PRODUCT: VINCRISTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 03:51:47
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 03:51:47
Data point term sent to Coder	System	05 Apr 2021 17:58:29
User entered 'VINCRISTINE'	Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 17:58:04
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'HIGH GRADE B CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'I'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 17:58:04
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'INJECTION'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'ONCE EVERY 3 WEEKS'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:58:04
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '11 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 17:58:04
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:58:04
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 17:58:04
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:58:04

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ALKYLATING AGENTS, ATC: NITROGEN MUSTARD ANALOGUES, PRODUCT: CYCLOPHOSPHAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 07:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:26:43
Data point term sent to Coder	System	05 Apr 2021 17:59:32
User entered 'CYCLOPHOSPHAMIDE'	Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 17:59:10
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'HIGH GRADE B CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'I'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 17:59:10
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'INJECTION'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'ONCE EVERY 3 WEEKS'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:59:10
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '11 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 17:59:10
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 17:59:10
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 17:59:10
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:59:10

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES, ATC: ANTHRACYCLINES AND RELATED SUBSTANCES, PRODUCT: DOXORUBICIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 07:33:45
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 07:33:45
Data point term sent to Coder	System	05 Apr 2021 18:01:37
User entered 'DOXORUBICIN'	Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 18:00:42
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'HIGH GRADE B CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'I'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 18:00:42
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'INJECTION'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'other (OTHER)'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 18:00:42
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'ONCE EVERY 3 WEEKS'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 18:00:42
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '11 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 18:00:42
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4)	05 Apr 2021 18:00:42
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 18:00:42
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 18:00:42
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:00:42

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: RITUXIMAB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:01:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:01:35
Data point term sent to Coder	System	05 Apr 2021 18:02:38
User entered 'RITUXIMAB'	Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 18:02:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'HIGH GRADE B CELL LYMPHOMA'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'I'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 18:02:11
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'INJECTION'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'other (OTHER)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'ONCE EVERY 3 WEEKS'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 18:02:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '11 Mar 2021'	(b) (4)	
	Amanda Horn (b) (4)	05 Apr 2021 18:02:11
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered empty.	(b) (4)	05 Apr 2021 18:02:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:48:28
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:22:57
User entered 'No (N)'	(b) (4)	05 Apr 2021 18:02:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:49:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:02:11

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:49:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:14
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:10:56

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '25 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:11:40

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'CT CHEST ABDOMEN PELVIS WITH IV CONTRAST AND ORAL CONTRAST'	(b) (4) Amanda Horn (b) (4)	25 Feb 2021 23:11:40

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
User entered 'Adverse Event (AE)'	Amanda Horn (b) (4)	25 Feb 2021 23:12:13
	(b) (4)	
	Amanda Horn (b) (4)	25 Feb 2021 23:11:40
	(b) (4)	

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:49:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4)	25 Feb 2021 23:11:40
	Amanda Horn (b) (4)	
	(b) (4)	

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:58
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '25 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:11:56

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:58
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'CHEST RADIOGRAPH'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Feb 2021 23:11:56

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:58
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	25 Feb 2021 23:12:04
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Amanda Horn (b) (4)	25 Feb 2021 23:11:56
	(b) (4)	

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:49:01

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:58
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:08:40
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	25 Feb 2021 23:11:56
	(b) (4)	

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:01

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered '26 Feb 2021'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:09:45

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered 'CERVICAL LYMPH NODE BIOPSY'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:09:45

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered 'Diagnostic (DIAGNOSTIC)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:09:45

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:49:01

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:40
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:09:45

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:01

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered '23 Dec 2020'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:34:52

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered 'CATARACT REMOVAL,RIGHT'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:34:52

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered 'Medical History (MH)'	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:34:52

US3752402

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:49:01

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:08:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	09 Mar 2021 18:34:52

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'USA-US113-2021-MRNA-1273-P301000006'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Priyantha'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Wijewardane'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'US'	(b) (4) System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	01 Apr 2021 15:07:15
User entered '4'	System	18 Mar 2021 15:41:50
User entered '3'	System	11 Mar 2021 15:01:25
User entered '2'	System	02 Mar 2021 14:43:58
User entered '1'	System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'USA-US113-2021-MRNA-1273-P301000006'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Priyantha'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Wijewardane'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'US'	(b) (4) System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	01 Apr 2021 15:07:15
User entered '4'	System	18 Mar 2021 15:41:50
User entered '3'	System	11 Mar 2021 15:01:25
User entered '2'	System	02 Mar 2021 14:43:58
User entered '1'	System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:49:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '26/Feb/2021 13:05'	(b) (4)	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:49:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'USA-US113-2021-MRNA-1273-P301000006'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Priyantha'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Wijewardane'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'US'	(b) (4) System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	01 Apr 2021 15:07:15
User entered '4'	System	18 Mar 2021 15:41:50
User entered '3'	System	11 Mar 2021 15:01:25
User entered '2'	System	02 Mar 2021 14:43:58
User entered '1'	System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:49:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered '02/Mar/2021 09:43'	(b) (4)	02 Mar 2021 14:43:58

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:49:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:43:58

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'USA-US113-2021-MRNA-1273-P301000006'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Priyantha'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Wijewardane'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'US'	(b) (4) System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	01 Apr 2021 15:07:15
User entered '4'	System	18 Mar 2021 15:41:50
User entered '3'	System	11 Mar 2021 15:01:25
User entered '2'	System	02 Mar 2021 14:43:58
User entered '1'	System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:49:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered '11/Mar/2021 07:01'	(b) (4)	11 Mar 2021 15:01:25
	System	

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:49:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:26:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:01:25

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'USA-US113-2021-MRNA-1273-P301000006'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Priyantha'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Wijewardane'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'US'	(b) (4) System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	01 Apr 2021 15:07:15
User entered '4'	System	18 Mar 2021 15:41:50
User entered '3'	System	11 Mar 2021 15:01:25
User entered '2'	System	02 Mar 2021 14:43:58
User entered '1'	System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:49:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:44:17
User entered '18/Mar/2021 11:41'	(b) (4)	18 Mar 2021 15:41:50

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:49:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:44:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:50

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'USA-US113-2021-MRNA-1273-P301000006'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Yes (Y)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'No (N)'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Priyantha'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:05:00
User entered 'Wijewardane'	System	26 Feb 2021 18:04:45

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:41:37
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:41:03
User entered 'US'	(b) (4) System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:49:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	01 Apr 2021 15:07:15
User entered '4'	System	18 Mar 2021 15:41:50
User entered '3'	System	11 Mar 2021 15:01:25
User entered '2'	System	02 Mar 2021 14:43:58
User entered '1'	System	26 Feb 2021 18:05:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:49:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered '01/Apr/2021 11:07'	(b) (4)	01 Apr 2021 15:07:15

US3752402

Folder: SAE USA-US113-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:49:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Apr 2021 04:39:44
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:26:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:07:15