

US3952141 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:30:47

All time stamps listed in this document are displayed in GMT

US3952141

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Participant ID

US3952141

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

US3952141

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3952141

Folder: Screening

Form: Demographics

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3952141

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Date of Informed Consent (<i>dd MMM yyyy</i>)	23 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

US3952141

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3952141

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Were any significant conditions reported?

Yes ☒
No ☐

US3952141

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3952141

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3952141

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952141

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3952141

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	SINUS HEADACHES
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)	

US3952141

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3952141

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Condition	LUMBAR SPONDYLOSIS
Start date (dd MMM yyyy)	UN JUN 2019
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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3952141

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:10 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:10
Height (<i>xxx.x</i>)	59.0 in
Weight (<i>xxx.x</i>)	153.0 lb
BMI (<i>xxx.x</i>)	30.96687 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)	

US3952141

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3952141

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*) 23 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2009

Date of last menstruation unknown False

US3952141

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

GROCERIES TWICE MONTHLY,
HUSBAND TAKES SIDE JOBS
WITH 4 PEOPLE. DAUGHTER
VISITS FOR
SEASONS/HOLIDAYS. CHURCH
ON SUNDAY. REAL ESTATE
LICENSE.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3952141

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

What was the date of randomization? (dd MMM yyyy) 23 SEP 2020

What was the participant's randomization number? 115244

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 ☒

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Height	ND - Not Done
Weight	ND - Not Done

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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)	23 SEP 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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)	23 SEP 2020
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 16:01
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3952141

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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.

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 15:01 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 15:01

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

US3952141

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	14:40 (24 HR)
Collection date and time (derived)	23 SEP 2020 14:40

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:34	23 SEP 2020 14:34
Nasopharyngeal Swab 2	No		

US3952141

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

98.0 °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

23 SEP 2020 16:02

PC Open Date & Time

23 SEP 2020 15:21

PC Close Date & Time

23 SEP 2020 17:51

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 98.2 °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	23 SEP 2020 22:10
PC Open Date & Time	23 SEP 2020 18:46
PC Close Date & Time	24 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 22:39

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 21:49

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

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

27 SEP 2020 22:26

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

98.2 °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

28 SEP 2020 22:02

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 23:33

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

23 SEP 2020 16:05

PC Open Date & Time

23 SEP 2020 15:21

PC Close Date & Time

23 SEP 2020 17:51

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 18:46

PC Close Date & Time

24 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 16:06
PC Open Date & Time	23 SEP 2020 15:21
PC Close Date & Time	23 SEP 2020 17:51

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 22:11
PC Open Date & Time	23 SEP 2020 18:46
PC Close Date & Time	24 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

51 of 2216

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3952141

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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)	28 OCT 2020
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 13:41
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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)	28 OCT 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 15:15
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3952141

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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.

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

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) 28 OCT 2020

What was the treatment time? (00:00-23:59) 14:29 (24 HR)

Treatment Date and Time (derived) 28 OCT 2020 14:29

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

US3952141

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

14:08 (24 HR)

Collection date and time (derived)

28 OCT 2020 14:08

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Collection date (<i>dd MMM yyyy</i>)			28 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	28 OCT 2020 14:12
Nasopharyngeal Swab 2	No		

US3952141

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:18

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

98.7 °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

28 OCT 2020 15:13

PC Open Date & Time

28 OCT 2020 14:49

PC Close Date & Time

28 OCT 2020 17:19

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 28 OCT 2020 18:14

PC Close Date & Time 29 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

30 OCT 2020 09:21

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

98.0 °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

30 OCT 2020 16:33

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

01 NOV 2020 12:52

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 21:12

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

28 OCT 2020 15:14

PC Open Date & Time

28 OCT 2020 14:49

PC Close Date & Time

28 OCT 2020 17:19

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 18:14

PC Close Date & Time

29 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

30 OCT 2020 09:22

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

30 OCT 2020 16:33

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

01 NOV 2020 12:52

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 21:15

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

No ☒

Yes ☐

PC Time stamp	28 OCT 2020 15:12
PC Open Date & Time	28 OCT 2020 14:49
PC Close Date & Time	28 OCT 2020 17:19

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 18:14

PC Close Date & Time

29 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

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 ☒

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 16:34
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

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 ☒

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 12:53
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

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 ☒

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 21:15
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

Yes ☐

PC Time stamp

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 8

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

Yes ☐

No ☐

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

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

PC Time stamp

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3952141

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3952141

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 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

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	15:40 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 15:40
Temperature (<i>xxx.x</i>)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952141

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

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.

US3952141

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

15:48 (24 HR)

Collection date and time (derived)

23 NOV 2020 15:48

US3952141

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	30 NOV 2020 21:20:25
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

14 DEC 2020 19:17:47

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 138

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 152

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

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02 MAR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

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09 MAR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

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16 MAR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 194

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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06 APR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 215

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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°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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 446

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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08 FEB 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

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

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15 FEB 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

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08 MAR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

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15 MAR 2022 23:59

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TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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Date and time of submission

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22 MAR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

US3952141

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Date and time of submission

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25 MAR 2022 00:01

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29 MAR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

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15 APR 2022 00:01

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19 APR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 621

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 <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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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="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"/>

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

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

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3952141

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:45:17

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3952141

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952141

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3952141

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

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.

US3952141

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3952141

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952141

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:30:47

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3952141

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

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3952141

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

Form: Unblinding

Generated On: 10 Jun 2021 10:30:47

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

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

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*)

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

US3952141

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3952141

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:30:47

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3952141

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:12:03

Generated On: 10 Jun 2021 10:30:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 20:21:49

Generated On: 10 Jun 2021 10:30:47

AEID	
Adverse event	VITAMIN D DEFICIENCY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 20:21:49

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 20:21:49

Generated On: 10 Jun 2021 10:30:47

AEID	USA-US215-2021-MRNA-1273-P30 1000006
Adverse event	WORSENING OF LUMBAR SPONDYLOSIS
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)	04 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)	10 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	16 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	354 of 2216

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 20:21:49

Generated On: 10 Jun 2021 10:30:47

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 20:21:49

Generated On: 10 Jun 2021 10:30:47

SUBJECT HOSPITALIZED
10MAR2021 FOR LUMBAR 4-5
SPINAL FUSION BECAUSE OF
WORSENING LUMBAR
SPONDYLOSIS. UNEVENTFUL
COURSE. DISCHARGED
18MAR2021 TO REHAB.
CURRENTLY IN REHAB. COVID
NEGATIVE X 2 TESTS IN
HOSPITAL.

FURTHER DETAILS UPON
RECEIPT OF MEDICAL
RECORDS.

UPON RECEIPT AND REVIEW OF
MEDICAL RECORDS CLARIFY
HOSPITAL DISCHARGE DATE.
ADMITTED 10MAR2021
DISCHARGED TO ACUTE
REHAB ON 16MAR2021.
SUBJECT WAS ADMITTED TO
HOSPITAL FOR WORSENING
LUMBAR SPONDYLOSIS WITH
SIGNIFICANT BACK PAIN WITH
RADICULOPATHY. SHE
UNDERWENT A L5-S1
TRANSFORAMINAL LUMBAR
INTERBODY FUSION (SPINAL
FUSION) ON 10MAR2021. SHE
HAD NO POST OPERATIVE
COMPLICATIONS AND
TOLERATED PHYSICAL
THERAPY WELL.
SHE

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 20:21:49

Generated On: 10 Jun 2021 10:30:47

TESTED NEG FOR COVID ON
15MAR2021.
HAD LUMBAR SPINE CT ON
11MAR2021 AND 13MAR2021
POST OPERATIVELY
REVEALING STABLE POST
FUSION.
HAD MRI OF SPINE 15MAR2021
REVEALING NO CAUDA
EQUINE COMPRESSION AND
EXPECTED L5-S1 POST OP
CHANGES.
WAS DISCHARGED TO ACUTE
REHAB ON 16MAR2021.

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 20:18:29

Generated On: 10 Jun 2021 10:30:47

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

Yes ☒

No ☐

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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 FEB 2019	
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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

365 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUMBAR
SPONDYLOSIS

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)

367 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)		04 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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

Dose per administration 650

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

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

PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication LIDOCAINE PATCH 4%

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

Dose per administration 1

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

If dose unit is Other, specify PATCH

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)

375 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication POST OP BG CONTROL

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 MAR 2021		
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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication ALBUTEROL MDI

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1.25/3

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

If dose unit is Other, specify MG/ML

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

379 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication CEFAZOLIN (ANCEF)

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE ANTIBIOTIC

Dose per administration 2/50

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 25/0.5

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication FLEET ENEMA

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 133

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 148

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

387 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication BENZOCAINE MENTHOL
LOZENGE

Prophylaxis Yes ☐
No ☒

Indication TOPICAL ANESTHESIA

Dose per administration 15/3.6

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

If dose unit is Other, specify MG/MG

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)

391 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication DIALAUDID

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN

Dose per administration 0.5/0.5

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

If dose unit is Other, specify MG/ML

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

393 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4/2

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

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

Q4HR PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)		10 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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING LUBAR
SPONDYLOSIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication DOCUSATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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 ☐

PRODUCTION RELEASE (v12.003

401 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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)	10 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication LACTULOSE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 10/5

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

If dose unit is Other, specify MG/ML

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

403 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 12 MAR 2021		
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"/>

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

Name of Medication LACTULOSE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 10/15

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

If dose unit is Other, specify G/ML

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

405 of 2216

EAB) (1725)

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 20:18:26

Generated On: 10 Jun 2021 10:30:47

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 MAR 2021		
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"/>

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:10:26

Generated On: 10 Jun 2021 10:30:47

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 20:18:29

Generated On: 10 Jun 2021 10:30:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 MAR 2021	LUMBAR 4-5 SPINAL FUSION [LUMBAR SPONDYLOLISTHESIS, L5-S1 STENOSIS, RADICULOPATHY, AND BACK PAIN]	Adverse Event	
11 MAR 2021	LUMBAR SPINE CT W/O CONTRAST FOR LUMBAR SPONDYLOSIS	Adverse Event	
13 MAR 2021	LUMBAR SPINE CT W/O CONTRAST FOR LUMBAR SPONDYLOSIS	Adverse Event	
15 MAR 2021	MRI SPINE W/O CONTRAST FOR LUMBAR SPONDYLOSIS	Adverse Event	

US3952141

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:30:47

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

US3952141

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:30:47

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 ☐

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 16:33:43

Generated On: 10 Jun 2021 10:30:47

SAEID	USA-US215-2021-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 16:33:43

Generated On: 10 Jun 2021 10:30:47

SAEID	USA-US215-2021-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 13:37
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

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 16:33:43

Generated On: 10 Jun 2021 10:30:47

SAEID	USA-US215-2021-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	31/MAR/2021 11:08
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

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 16:33:43

Generated On: 10 Jun 2021 10:30:47

SAEID	USA-US215-2021-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/APR/2021 10:43
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

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 16:33:43

Generated On: 10 Jun 2021 10:30:47

SAEID	USA-US215-2021-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/APR/2021 08:57
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

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 16:33:43

Generated On: 10 Jun 2021 10:30:47

SAEID	USA-US215-2021-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIMI
Investigator's Last Name	VAN DER LEDEN
Site Address: Street	15201 SHADY GROVE DR
Site Address: City	ROCKVILLE
Site Address: State	
Site Address: Postal Code	20850
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 09:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3952141 (Prod: Synexus - Optimal Research - Rockville)

US3952141

Form: Participant Creation

Generated On: 10 Jun 2021 10:30:47

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:15:22
User entered 'US3952141'	RWS_ENDPOINT	23 Sep 2020 17:34:24
	ENDPOINT (b) (4)	

US3952141

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:57:16
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:13

US3952141

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:57:16
User entered '23 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 17:34:25

US3952141

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:57:16
User entered 'Clinic (Clinic)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:13

US3952141

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'SCRN'	System	23 Sep 2020 19:46:13

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 17:34:26

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '63'	Nick Bart (b) (4) (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered 'YEARS'	System	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered '63'	System	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered 'Female (F)'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered 'I'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:30:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 18:58:29
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:07:42

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered '23 Sep 2020'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered 'Sep 2020'	System	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered '2020'	System	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered 'Amendment 3 (3)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered empty.	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered empty.	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered 'No (N)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 17:34:25

US3952141

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:30:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered 'I'	System	23 Sep 2020 19:46:30

US3952141

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:11:00
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:46:30

US3952141

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:30:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:23
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:10:32

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:01
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	(b) (4) Coders Import (b) (4)	29 Dec 2020 18:54:20
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4)	29 Dec 2020 18:54:20
Data point term sent to Coders	System	29 Dec 2020 18:53:43
Coding entries removed.	Nick Bart (b) (4)	29 Dec 2020 18:53:20
User entered 'seasonal ALLERGIES' reason for change: Per Query Resolution	Nick Bart (b) (4)	29 Dec 2020 18:53:20
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Multiple allergies, LLT: Multiple allergies - version MedDRA\23.0.	Coders Import (b) (4)	15 Oct 2020 19:46:26
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4)	15 Oct 2020 19:46:26
Data point term sent to Coders	System	15 Oct 2020 19:45:31
User closed query 'For coding purposes, please enter the type of ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' (Site from System).	System	15 Oct 2020 19:45:10
Query 'For coding purposes, please enter the type of ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' answered with 'term updated per query instructions.' (Site from System).	Nick Bart (b) (4)	15 Oct 2020 19:45:10
User entered 'multiple ALLERGIES' reason for change: Per Query Resolution	Nick Bart (b) (4)	15 Oct 2020 19:44:57

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 19:18:51
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:18:37
User opened query 'For coding purposes, please enter the type of ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' (Site from System).	Coder Import (b) (4)	25 Sep 2020 16:28:45
Data point term sent to Coder	System	25 Sep 2020 14:11:37
User entered 'allergies'	Nick Bart (b) (4)	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered 'un UNK 2017'	Nick Bart (b) (4)	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jan 2017'	System	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '2017'	System	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:10:45

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:12:48
Data point term sent to Coder	System	25 Sep 2020 14:11:38
User entered 'latex allergy'	Nick Bart (b) (4)	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered 'un UNK 1975'	Nick Bart (b) (4)	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jan 1975'	System	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '1975'	System	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:10:58

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:12:48
Data point term sent to Coder	System	25 Sep 2020 14:11:37
User entered 'sulfa allergy'	Nick Bart (b) (4)	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered 'un UNK 1975'	Nick Bart (b) (4)	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:18:37
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jan 1975'	System	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '1975'	System	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:11:08

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Dec 2020 18:55:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:55:21
Data point term sent to Coder	System	29 Dec 2020 18:54:44
User entered 'headaches'	Nick Bart (b) (4)	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'un UNK 1978'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jan 1978'	System	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '1978'	System	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	29 Dec 2020 18:53:45

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Sinus headache, LLT: Sinus headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Dec 2020 18:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 18:55:20
Data point term sent to Coder	System	29 Dec 2020 18:54:44
User entered 'sinus headaches'	Nick Bart (b) (4)	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'un UNK 2010'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jan 2010'	System	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '2010'	System	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	29 Dec 2020 18:53:57

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Dec 2020 18:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:55:20
Data point term sent to Coder	System	29 Dec 2020 18:54:44
User entered 'postmenopausal'	Nick Bart (b) (4)	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'un UNK 2009'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty.	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jan 2009'	System	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '2009'	System	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	29 Dec 2020 18:54:15

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Lumbar spondylosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 19:13:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:13:58
Data point term sent to Coder	System	05 Apr 2021 19:12:35
User entered 'Lumbar Spondylosis'	(b) (4), (b) (6)	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'un Jun 2019'	(b) (4), (b) (6)	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:57:34
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'Jun 2019'	System	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '2019'	System	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	05 Apr 2021 19:11:59

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:15:35
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:15:37
User entered '23 Sep 2020'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:15:39
User entered '13:10'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '23 Sep 2020 13:10'	System	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:16:34
User entered '59.0' in	Nick Bart (b) (4)	25 Sep 2020 14:10:20
DataPoint set to visible.	System	23 Sep 2020 19:46:30

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:16:42
User entered '153.0' lb	Nick Bart (b) (4)	25 Sep 2020 14:10:20
DataPoint set to visible.	System	23 Sep 2020 19:46:30

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '30.96687'	System	25 Sep 2020 14:10:20
DataPoint set to visible.	System	23 Sep 2020 19:46:30

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'kg/m2'	System	25 Sep 2020 14:10:20
DataPoint set to visible.	System	23 Sep 2020 19:46:30

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:43:58
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	15 Oct 2020 19:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:45:44
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:17:34
User entered '36.8' C	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	15 Oct 2020 19:45:44
User entered 'Oral (Oral)'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:45:44
User entered '71'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'bpm'	System	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:45:44
User entered '12'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'breaths/min'	System	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:45:44
User entered '147'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'mmHg'	System	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:45:44
User entered '93'	Nick Bart (b) (4)	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'mmHg'	System	25 Sep 2020 14:10:20

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30

US3952141

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30

US3952141

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:22:41
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:09:45

US3952141

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:22:41
User entered '23 Sep 2020'	Nick Bart (b) (4)	25 Sep 2020 14:09:45

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:38
User entered '23 Sep 2020'	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:40
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 09:50:24
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'MH updated' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:57:27
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:14:50
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:42:44
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:58
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:58
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:58
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:58
User entered 'un UNK 2009'	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:30:47

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:14:58
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:09:39

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'groceries twice monthly, husband takes side jobs with 4 people. daughter visits for seasons/holidays. church on sunday. real estate license.'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered 'I'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '0'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:30:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:58:55
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:09:12

US3952141

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:24
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:11:18

US3952141

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:24
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered '23 Sep 2020'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:11:18

US3952141

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:24
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:11:18

US3952141

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'VISIT1'	System	25 Sep 2020 14:11:18

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered '23 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 18:24:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered '115244'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 18:24:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 18:24:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:11:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

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)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:11:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:11:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:11:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:11:25

US3952141

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:30:47

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:19:41
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:11:25
DataPoint set to visible.	System	23 Sep 2020 19:46:25

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:30:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:31:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:43:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:46:13
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	15 Oct 2020 19:46:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:55
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:17:44
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:30:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:31:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:46:13
DataPoint Un-verified.	Nick Bart (b) (4)	09 Oct 2020 19:23:57
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:30:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:31:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:43:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:46:13
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	15 Oct 2020 19:46:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:55
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:17:44
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:30:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:31:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:46:13
DataPoint Un-verified.	Nick Bart (b) (4)	09 Oct 2020 19:23:57
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:49:47
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	15 Oct 2020 19:47:29
DataPoint Un-verified.	Nick Bart (b) (4)	15 Oct 2020 19:47:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Pre-Dose Vital Signs should be recorded at Visit 1 Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:17:59
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Un-verified.	(b) (4)	15 Oct 2020 19:47:25
User entered '23 Sep 2020' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Un-verified.	(b) (4)	15 Oct 2020 19:47:25
User entered '13:10' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '23 Sep 2020 13:10'	System	15 Oct 2020 19:47:25
User entered empty.	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Un-verified.	(b) (4)	15 Oct 2020 19:47:25
User entered '36.8' C reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Un-verified.	(b) (4)	15 Oct 2020 19:47:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Un-verified.	(b) (4)	15 Oct 2020 19:47:25
User entered '71' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'bpm'	System	15 Oct 2020 19:47:25
User entered empty.	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Un-verified.	(b) (4)	15 Oct 2020 19:47:25
User entered '12' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'breaths/min'	System	15 Oct 2020 19:47:25
User entered empty.	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:14:48
Query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:59:03
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP \leq 89 or \geq 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 03:10:06
DataPoint Un-verified.	Nick Bart (b) (4)	15 Oct 2020 19:47:25
User entered '147' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'mmHg'	System	15 Oct 2020 19:47:25
User entered empty.	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:54:57
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:14:50
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:59:12
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 03:10:17
DataPoint Un-verified.	Nick Bart (b) (4)	15 Oct 2020 19:47:25
User entered '93' reason for change: Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:47:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'mmHg'	System	15 Oct 2020 19:47:25
User entered empty.	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:30:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:31:26
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User closed query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 08:43:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Nick Bart (b) (4)	15 Oct 2020 19:46:13
Query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	15 Oct 2020 19:46:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:55
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User opened query 'Per CDM: Per CCGs Version 2.0 pages 16 & 17, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' at Day 1. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:17:44
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:30:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:31:29
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Oct 2020 19:46:13
DataPoint Un-verified.	Nick Bart (b) (4)	09 Oct 2020 19:23:57
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '23 Sep 2020'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '16:01'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '23 Sep 2020 16:01'	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '36.7' C	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered 'Oral (Oral)'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '72'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'bpm'	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '12'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'breaths/min'	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '126'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'mmHg'	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:23:50
User entered '86'	Nick Bart (b) (4)	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'mmHg'	System	25 Sep 2020 14:12:50

US3952141

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:55:53
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:11:29

US3952141

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:55:53
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered empty.	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:11:29

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered 'Yes (Y)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered empty.	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered empty.	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered '23 Sep 2020'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered '15:01'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '23 Sep 2020 15:01'	System	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered 'Right Arm (RIGHT ARM)'	Stephanie Melton (b) (4) (b) (4)	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:22:34
User entered 'ONCE'	System	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 19:47:15

US3952141

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:20:53
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:11:48

US3952141

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:20:53
User entered '23 Sep 2020'	Nick Bart (b) (4)	25 Sep 2020 14:11:48

US3952141

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:20:53
User entered '14:40'	Nick Bart (b) (4)	25 Sep 2020 14:11:48

US3952141

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '23 Sep 2020 14:40'	System	25 Sep 2020 14:11:48

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:21:07
User entered '23 Sep 2020'	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:21:07
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:21:07
User entered '14:34'	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered '23 Sep 2020 14:34'	System	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:21:07
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:21:07
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered empty.	System	25 Sep 2020 14:12:03

US3952141

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:56:27
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	25 Sep 2020 14:11:33

US3952141

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:30
User entered 'I'	System	25 Sep 2020 14:11:33

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:02:13', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e57db001-4998-40dd-99de-feec251994b8' User entered 'Yes (Y)'	System	23 Sep 2020 20:02:39
	System	23 Sep 2020 20:02:39

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:02:22', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e57db001-4998-40dd-99de-feec251994b8' User entered '98.0'	System	23 Sep 2020 20:02:39
	System	23 Sep 2020 20:02:39

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:02:28', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e57db001-4998-40dd-99de-feec251994b8'	System	23 Sep 2020 20:02:39
User entered 'No (N)'	System	23 Sep 2020 20:02:39

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:02:33', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e57db001-4998-40dd-99de-feec251994b8' User entered '23 Sep 2020 16:02'	System	23 Sep 2020 20:02:39
	System	23 Sep 2020 20:02:39

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 15:21'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 17:51'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:10:21', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'b430e7d6-8ccb-4053-8194-591ab0903842'	System	24 Sep 2020 02:10:38
User entered 'Yes (Y)'	System	24 Sep 2020 02:10:38

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:10:27', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'b430e7d6-8ccb-4053-8194-591ab0903842'	System	24 Sep 2020 02:10:38
User entered '98.2'	System	24 Sep 2020 02:10:38

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:10:13', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'b430e7d6-8ccb-4053-8194-591ab0903842'	System	24 Sep 2020 02:10:38
User entered 'No (N)'	System	24 Sep 2020 02:10:38

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:10:34', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'b430e7d6-8ccb-4053-8194-591ab0903842'	System	24 Sep 2020 02:10:38
User entered '23 Sep 2020 22:10'	System	24 Sep 2020 02:10:38

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 18:46'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Protocol deviation created: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) Class: Other Code: Deviation.	(b) (4), (b) (6)	09 Oct 2020 19:28:25
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 2'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 3'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-25T22:39:01', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '506e6a19-3368-4d43-a1b5-c168ec1ea6ef' User entered 'Yes (Y)'	System	26 Sep 2020 02:39:13
	System	26 Sep 2020 02:39:13

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-25T22:38:49', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '506e6a19-3368-4d43-a1b5-c168ec1ea6ef' User entered '99.8'	System	26 Sep 2020 02:39:13
	System	26 Sep 2020 02:39:13

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-25T22:38:54', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '506e6a19-3368-4d43-a1b5-c168ec1ea6ef' User entered 'No (N)'	System	26 Sep 2020 02:39:13
	System	26 Sep 2020 02:39:13

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-25T22:39:09', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '506e6a19-3368-4d43-a1b5-c168ec1ea6ef' User entered '25 Sep 2020 22:39'	System	26 Sep 2020 02:39:13
	System	26 Sep 2020 02:39:13

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 4'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-26T21:48:20', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '51af8f72-35cf-48eb-86af-8df78b847999'	System	27 Sep 2020 01:49:09
User entered 'Yes (Y)'	System	27 Sep 2020 01:49:09

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-26T21:48:53', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '51af8f72-35cf-48eb-86af-8df78b847999'	System	27 Sep 2020 01:49:09
User entered '98.3'	System	27 Sep 2020 01:49:09

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-26T21:49:00', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '51af8f72-35cf-48eb-86af-8df78b847999'	System	27 Sep 2020 01:49:09
User entered 'No (N)'	System	27 Sep 2020 01:49:09

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-26T21:49:07', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '51af8f72-35cf-48eb-86af-8df78b847999'	System	27 Sep 2020 01:49:09
User entered '26 Sep 2020 21:49'	System	27 Sep 2020 01:49:09

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 5'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-27T22:26:05', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '978bb690-ea2d-4752-9276-379b4c6cc2ad' User entered 'Yes (Y)'	System	28 Sep 2020 02:26:37
	System	28 Sep 2020 02:26:37

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-27T22:26:20', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '978bb690-ea2d-4752-9276-379b4c6cc2ad' User entered '99.0'	System	28 Sep 2020 02:26:37
	System	28 Sep 2020 02:26:37

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-27T22:26:28', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '978bb690-ea2d-4752-9276-379b4c6cc2ad' User entered 'No (N)'	System	28 Sep 2020 02:26:37
	System	28 Sep 2020 02:26:37

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-27T22:26:35', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '978bb690-ea2d-4752-9276-379b4c6cc2ad' User entered '27 Sep 2020 22:26'	System	28 Sep 2020 02:26:37
	System	28 Sep 2020 02:26:37

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 6'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-28T22:02:13', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '705c24ae-4f3c-4d7a-86ed-7b5b04f11a5d' User entered 'Yes (Y)'	System	29 Sep 2020 02:03:00
	System	29 Sep 2020 02:03:00

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-28T22:02:44', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '705c24ae-4f3c-4d7a-86ed-7b5b04f11a5d' User entered '98.2'	System	29 Sep 2020 02:03:00
	System	29 Sep 2020 02:03:00

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-28T22:02:48', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '705c24ae-4f3c-4d7a-86ed-7b5b04f11a5d'	System	29 Sep 2020 02:03:00
User entered 'No (N)'	System	29 Sep 2020 02:03:00

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-28T22:02:55', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '705c24ae-4f3c-4d7a-86ed-7b5b04f11a5d'	System	29 Sep 2020 02:03:00
User entered '28 Sep 2020 22:02'	System	29 Sep 2020 02:03:00

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 7'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-29T23:32:46', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '6d9ae744-af0a-484b-9492-93dc04a40a77'	System	30 Sep 2020 03:33:12
User entered 'Yes (Y)'	System	30 Sep 2020 03:33:12

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-29T23:32:56', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '6d9ae744-af0a-484b-9492-93dc04a40a77' User entered '97.2'	System	30 Sep 2020 03:33:12
	System	30 Sep 2020 03:33:12

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-29T23:33:01', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '6d9ae744-af0a-484b-9492-93dc04a40a77'	System	30 Sep 2020 03:33:12
User entered 'No (N)'	System	30 Sep 2020 03:33:12

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-29T23:33:10', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '6d9ae744-af0a-484b-9492-93dc04a40a77'	System	30 Sep 2020 03:33:12
User entered '29 Sep 2020 23:33'	System	30 Sep 2020 03:33:12

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:04:50', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '9fff3d8e-30be-446b-b96f-4f527094d107'	System	23 Sep 2020 20:05:47
User entered 'None (1)'	System	23 Sep 2020 20:05:47

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:04:57', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '9fff3d8e-30be-446b-b96f-4f527094d107'	System	23 Sep 2020 20:05:47
User entered 'No (N)'	System	23 Sep 2020 20:05:47

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:03', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '9fff3d8e-30be-446b-b96f-4f527094d107' User entered 'No (N)'	System	23 Sep 2020 20:05:47
	System	23 Sep 2020 20:05:47

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:11', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '9fff3d8e-30be-446b-b96f-4f527094d107'	System	23 Sep 2020 20:05:47
User entered 'None (1)'	System	23 Sep 2020 20:05:47

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:27', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '9fff3d8e-30be-446b-b96f-4f527094d107'	System	23 Sep 2020 20:05:47
User entered '23 Sep 2020 16:05'	System	23 Sep 2020 20:05:47

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 15:21'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 17:51'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 18:46'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 2'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 3'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 4'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 5'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 6'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 7'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:36', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6' User entered 'None (0)'	System	23 Sep 2020 20:06:24
	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:42', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6' User entered 'None (0)'	System	23 Sep 2020 20:06:24
	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:47', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6' User entered 'None (0)'	System	23 Sep 2020 20:06:24
	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:52', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6' User entered 'None (0)'	System	23 Sep 2020 20:06:24
	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:56', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6' User entered 'None (0)'	System	23 Sep 2020 20:06:24
	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:05:59', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6' User entered 'None (0)'	System	23 Sep 2020 20:06:24
	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:06:09', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6'	System	23 Sep 2020 20:06:24
User entered 'No (N)'	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T16:06:23', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4dbfe63b-3a5e-439b-9fd1-ea08ab0987a6'	System	23 Sep 2020 20:06:24
User entered '23 Sep 2020 16:06'	System	23 Sep 2020 20:06:24

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 15:21'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 17:51'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:13', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered 'None (0)'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:17', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered 'None (0)'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:22', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered 'None (0)'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:26', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered 'None (0)'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:30', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered 'None (0)'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:34', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered 'None (0)'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:38', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16'	System	24 Sep 2020 02:11:45
User entered 'No (N)'	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (219FC5BB-9CEB-4009-8E70-01F4CC9AA63A)', Time: '2020-09-23T22:11:42', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '16b10e60-0372-4ba0-87a4-233d695f7d16' User entered '23 Sep 2020 22:11'	System	24 Sep 2020 02:11:45
	System	24 Sep 2020 02:11:45

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '23 Sep 2020 18:46'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 2'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 3'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 4'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 5'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 6'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	23 Sep 2020 19:47:15
User entered 'Day 7'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:47:15

US3952141

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:47:15

US3952141

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:21
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Oct 2020 15:40:02

US3952141

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:21
User entered '01 Oct 2020'	Nick Bart (b) (4)	05 Oct 2020 15:40:02

US3952141

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:21
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4)	05 Oct 2020 15:40:02

US3952141

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:21
User entered empty.	Nick Bart (b) (4)	05 Oct 2020 15:40:02

US3952141

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:24
User entered 'Yes (Y)'	Nick Bart (b) (4)	05 Oct 2020 15:39:54

US3952141

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered 'I'	System	05 Oct 2020 15:39:54

US3952141

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:33
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 19:42:18

US3952141

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:33
User entered '08 Oct 2020'	Nick Bart (b) (4)	13 Oct 2020 19:42:18

US3952141

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:33
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4)	13 Oct 2020 19:42:18

US3952141

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:33
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 19:42:18

US3952141

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:37
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 19:42:06

US3952141

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered 'I'	System	13 Oct 2020 19:42:06

US3952141

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:46
User entered 'Yes (Y)'	Nick Bart (b) (4)	15 Oct 2020 19:43:57

US3952141

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:46
User entered '14 Oct 2020'	Nick Bart (b) (4)	15 Oct 2020 19:43:57

US3952141

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:46
User entered 'Contact Made (CONTACT MADE)'	Nick Bart (b) (4)	15 Oct 2020 19:43:57

US3952141

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:46
User entered empty.	Nick Bart (b) (4)	15 Oct 2020 19:43:57

US3952141

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:40:49
User entered 'Yes (Y)'	Nick Bart (b) (4)	15 Oct 2020 19:43:50

US3952141

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:50:28
User entered 'I'	System	15 Oct 2020 19:43:50

US3952141

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:41:50
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Oct 2020 14:38:35

US3952141

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:41:50
User entered '28 Oct 2020'	Nick Bart (b) (4)	29 Oct 2020 14:38:35

US3952141

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:41:50
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	29 Oct 2020 14:38:35

US3952141

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'VISIT2'	System	29 Oct 2020 14:38:35

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '28 Oct 2020'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '13:41'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '28 Oct 2020 13:41'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '37.2' C	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered 'Oral (Oral)'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered empty.	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '76'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'bpm'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '14'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'breaths/min'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '139'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'mmHg'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:15:11
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:59:53
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:53:43
User entered '97'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'mmHg'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '28 Oct 2020'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '15:15'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '28 Oct 2020 15:15'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '37.1' C	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered 'Oral (Oral)'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered empty.	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '85'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'bpm'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '14'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'breaths/min'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '119'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'mmHg'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:55
User entered '84'	Nick Bart (b) (4)	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'mmHg'	System	29 Oct 2020 14:39:34

US3952141

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:42:40
User entered 'No (N)'	Nick Bart (b) (4)	29 Oct 2020 14:37:26

US3952141

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:42:40
User entered empty.	Nick Bart (b) (4)	29 Oct 2020 14:37:26

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered 'Yes (Y)'	Atanas Filev (b) (4) (b) (4)	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered empty.	Atanas Filev (b) (4) (b) (4)	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered empty.	Atanas Filev (b) (4) (b) (4)	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'MRNA-1273 OR PLACEBO'	System	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered '28 Oct 2020'	Atanas Filev (b) (4) (b) (4)	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered '14:29'	Atanas Filev (b) (4) (b) (4)	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '28 Oct 2020 14:29'	System	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered 'Right Arm (RIGHT ARM)'	Atanas Filev (b) (4) (b) (4)	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:44:09
User entered 'ONCE'	System	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:30:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'INTRAMUSCULAR'	System	28 Oct 2020 19:06:51

US3952141

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:14
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Oct 2020 14:38:14

US3952141

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden (b) (4)	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:46:14
User closed query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "Confirmed", however, please also confirm that the PPD portal was update in the query response, as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:26:07
Query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "Confirmed", however, please also confirm that the PPD portal was update in the query response, as appropriate.' answered with 'PPD portal up to date' (Site from DM).	Nick Bart (b) (4)	13 Jan 2021 19:40:32
User opened query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "Confirmed", however, please also confirm that the PPD portal was update in the query response, as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 14:42:38
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:52:08
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' answered with 'Confirmed' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:59:28
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:34:19
User entered '28 Oct 2020'	Nick Bart (b) (4)	29 Oct 2020 14:38:14

US3952141

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:14
User entered '14:08'	Nick Bart (b) (4)	29 Oct 2020 14:38:14

US3952141

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '28 Oct 2020 14:08'	System	29 Oct 2020 14:38:14

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:30:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:19
User entered '28 Oct 2020'	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:19
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:19
User entered '14:12'	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '28 Oct 2020 14:12'	System	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:19
User entered 'No (N)'	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:19
User entered empty.	Nick Bart (b) (4)	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered empty.	System	29 Oct 2020 14:38:27

US3952141

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:46:25
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Oct 2020 14:37:56

US3952141

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'I'	System	29 Oct 2020 14:37:56

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:12:53', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '38c3adc1-48fd-478b-ad4f-3d7b2d93cf71'	System	28 Oct 2020 19:13:12
User entered 'Yes (Y)'	System	28 Oct 2020 19:13:12

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:12:59', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '38c3adc1-48fd-478b-ad4f-3d7b2d93cf71'	System	28 Oct 2020 19:13:12
User entered '98.7'	System	28 Oct 2020 19:13:12

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:13:03', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '38c3adc1-48fd-478b-ad4f-3d7b2d93cf71'	System	28 Oct 2020 19:13:12
User entered 'No (N)'	System	28 Oct 2020 19:13:12

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:13:10', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '38c3adc1-48fd-478b-ad4f-3d7b2d93cf71'	System	28 Oct 2020 19:13:12
User entered '28 Oct 2020 15:13'	System	28 Oct 2020 19:13:12

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '28 Oct 2020 14:49'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '28 Oct 2020 17:19'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '28 Oct 2020 18:14'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 2'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:21:31', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e492b034-48d5-4dd3-9ae5-3935f9cf3b78'	System	30 Oct 2020 13:21:55
User entered 'Yes (Y)'	System	30 Oct 2020 13:21:55

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:21:40', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e492b034-48d5-4dd3-9ae5-3935f9cf3b78'	System	30 Oct 2020 13:21:55
User entered '97.7'	System	30 Oct 2020 13:21:55

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:21:44', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e492b034-48d5-4dd3-9ae5-3935f9cf3b78'	System	30 Oct 2020 13:21:55
User entered 'No (N)'	System	30 Oct 2020 13:21:55

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:21:50', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'e492b034-48d5-4dd3-9ae5-3935f9cf3b78'	System	30 Oct 2020 13:21:55
User entered '30 Oct 2020 09:21'	System	30 Oct 2020 13:21:55

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 3'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:32:58', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '93d57c46-d23c-4b99-9a04-588fbede236c'	System	30 Oct 2020 20:34:26
User entered 'Yes (Y)'	System	30 Oct 2020 20:34:26

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:06', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '93d57c46-d23c-4b99-9a04-588fbede236c'	System	30 Oct 2020 20:34:26
User entered '98.0'	System	30 Oct 2020 20:34:26

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:10', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '93d57c46-d23c-4b99-9a04-588fbede236c'	System	30 Oct 2020 20:34:26
User entered 'No (N)'	System	30 Oct 2020 20:34:26

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:18', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '93d57c46-d23c-4b99-9a04-588fbede236c'	System	30 Oct 2020 20:34:26
User entered '30 Oct 2020 16:33'	System	30 Oct 2020 20:34:26

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 4'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 5'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:51:36', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd3c484f0-fcab-4e49-8006-d744ae457347'	System	01 Nov 2020 17:52:07
User entered 'Yes (Y)'	System	01 Nov 2020 17:52:07

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:51:55', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd3c484f0-fcab-4e49-8006-d744ae457347'	System	01 Nov 2020 17:52:07
User entered '97.4'	System	01 Nov 2020 17:52:07

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:51:58', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd3c484f0-fcab-4e49-8006-d744ae457347'	System	01 Nov 2020 17:52:07
User entered 'No (N)'	System	01 Nov 2020 17:52:07

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:03', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd3c484f0-fcab-4e49-8006-d744ae457347'	System	01 Nov 2020 17:52:07
User entered '01 Nov 2020 12:52'	System	01 Nov 2020 17:52:07

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 6'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:11:51', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '21fc336a-ad63-4f9f-b800-98168e856a1f'	System	03 Nov 2020 02:12:14
User entered 'Yes (Y)'	System	03 Nov 2020 02:12:14

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:12:02', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '21fc336a-ad63-4f9f-b800-98168e856a1f'	System	03 Nov 2020 02:12:14
User entered '97.6'	System	03 Nov 2020 02:12:14

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:12:06', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '21fc336a-ad63-4f9f-b800-98168e856a1f'	System	03 Nov 2020 02:12:14
User entered 'No (N)'	System	03 Nov 2020 02:12:14

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:12:11', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '21fc336a-ad63-4f9f-b800-98168e856a1f'	System	03 Nov 2020 02:12:14
User entered '02 Nov 2020 21:12'	System	03 Nov 2020 02:12:14

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 7'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:23:38

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:38
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:13:50', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '49e37b30-95c0-43d1-89ad-68ed491fb5dd'	System	28 Oct 2020 19:14:34
User entered 'None (1)'	System	28 Oct 2020 19:14:34

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:14:17', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '49e37b30-95c0-43d1-89ad-68ed491fb5dd'	System	28 Oct 2020 19:14:34
User entered 'No (N)'	System	28 Oct 2020 19:14:34

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:14:21', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '49e37b30-95c0-43d1-89ad-68ed491fb5dd'	System	28 Oct 2020 19:14:34
User entered 'No (N)'	System	28 Oct 2020 19:14:34

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:14:26', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '49e37b30-95c0-43d1-89ad-68ed491fb5dd'	System	28 Oct 2020 19:14:34
User entered 'None (1)'	System	28 Oct 2020 19:14:34

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:14:30', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '49e37b30-95c0-43d1-89ad-68ed491fb5dd'	System	28 Oct 2020 19:14:34
User entered '28 Oct 2020 15:14'	System	28 Oct 2020 19:14:34

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Oct 2020 14:49'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Oct 2020 17:19'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Oct 2020 18:14'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 2'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:22:01', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '53e52ca0-e208-43a7-9176-0d26f53c68d0'	System	30 Oct 2020 13:22:38
User entered 'None (1)'	System	30 Oct 2020 13:22:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:22:11', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '53e52ca0-e208-43a7-9176-0d26f53c68d0'	System	30 Oct 2020 13:22:38
User entered 'No (N)'	System	30 Oct 2020 13:22:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:22:15', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '53e52ca0-e208-43a7-9176-0d26f53c68d0'	System	30 Oct 2020 13:22:38
User entered 'No (N)'	System	30 Oct 2020 13:22:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:22:25', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '53e52ca0-e208-43a7-9176-0d26f53c68d0'	System	30 Oct 2020 13:22:38
User entered 'None (1)'	System	30 Oct 2020 13:22:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T09:22:32', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '53e52ca0-e208-43a7-9176-0d26f53c68d0'	System	30 Oct 2020 13:22:38
User entered '30 Oct 2020 09:22'	System	30 Oct 2020 13:22:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 3'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:25', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4cab03d0-6b76-49c6-99f5-fa3ae3011811'	System	30 Oct 2020 20:34:45
User entered 'None (1)'	System	30 Oct 2020 20:34:45

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:29', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4cab03d0-6b76-49c6-99f5-fa3ae3011811'	System	30 Oct 2020 20:34:45
User entered 'No (N)'	System	30 Oct 2020 20:34:45

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:36', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4cab03d0-6b76-49c6-99f5-fa3ae3011811'	System	30 Oct 2020 20:34:45
User entered 'No (N)'	System	30 Oct 2020 20:34:45

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:42', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4cab03d0-6b76-49c6-99f5-fa3ae3011811'	System	30 Oct 2020 20:34:45
User entered 'None (1)'	System	30 Oct 2020 20:34:45

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:33:51', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '4cab03d0-6b76-49c6-99f5-fa3ae3011811'	System	30 Oct 2020 20:34:45
User entered '30 Oct 2020 16:33'	System	30 Oct 2020 20:34:45

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 4'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 5'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:10', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '3e27332f-a7c9-45e8-9b8a-a2f20a3c872c'	System	01 Nov 2020 17:52:38
User entered 'None (1)'	System	01 Nov 2020 17:52:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:14', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '3e27332f-a7c9-45e8-9b8a-a2f20a3c872c'	System	01 Nov 2020 17:52:38
User entered 'No (N)'	System	01 Nov 2020 17:52:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:21', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '3e27332f-a7c9-45e8-9b8a-a2f20a3c872c'	System	01 Nov 2020 17:52:38
User entered 'No (N)'	System	01 Nov 2020 17:52:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:26', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '3e27332f-a7c9-45e8-9b8a-a2f20a3c872c'	System	01 Nov 2020 17:52:38
User entered 'None (1)'	System	01 Nov 2020 17:52:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:34', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '3e27332f-a7c9-45e8-9b8a-a2f20a3c872c'	System	01 Nov 2020 17:52:38
User entered '01 Nov 2020 12:52'	System	01 Nov 2020 17:52:38

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 6'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:12:18', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered 'None (1)'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:12:21', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered 'Yes (Y)'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:14:24', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered '1'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:14:30', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered 'Yes (Y)'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:00', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered '1'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:03', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered 'None (1)'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:07', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '28923c6d-cb56-4c9f-b220-bea7c6b5d9f3'	System	03 Nov 2020 02:15:12
User entered '02 Nov 2020 21:15'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 7'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:11:41', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'None (0)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:11:45', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'None (0)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:11:51', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'None (0)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:11:56', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'None (0)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:12:01', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'None (0)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:12:05', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'None (0)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:12:14', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered 'No (N)'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-28T15:12:19', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '8a046e64-3196-4d5a-bd5c-8ef972dac285'	System	28 Oct 2020 19:12:22
User entered '28 Oct 2020 15:12'	System	28 Oct 2020 19:12:22

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Oct 2020 14:49'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Oct 2020 17:19'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '28 Oct 2020 18:14'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 2'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 3'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:09', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'None (0)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:12', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'None (0)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:20', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'None (0)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:23', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'None (0)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:25', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'None (0)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:28', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'None (0)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:31', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered 'No (N)'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-10-30T16:34:37', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd240b993-7f30-4a54-84dc-945f832df9de'	System	30 Oct 2020 20:35:16
User entered '30 Oct 2020 16:34'	System	30 Oct 2020 20:35:16

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 4'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 5'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:45', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'None (0)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:48', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'None (0)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:51', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'None (0)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:53', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'None (0)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:56', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'None (0)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:52:58', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'None (0)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:53:02', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered 'No (N)'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-01T12:53:11', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '1f7224ea-57ab-41a7-9d09-697988b3a274'	System	01 Nov 2020 17:53:14
User entered '01 Nov 2020 12:53'	System	01 Nov 2020 17:53:14

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 6'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:16', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'None (0)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:18', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'None (0)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:20', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'None (0)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:22', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'None (0)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:24', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'None (0)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:26', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'None (0)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:29', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered 'No (N)'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-02T21:15:32', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'da032311-d8c1-4018-ab04-a17abc6e5322'	System	03 Nov 2020 02:15:34
User entered '02 Nov 2020 21:15'	System	03 Nov 2020 02:15:34

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	28 Oct 2020 19:06:51
User entered 'Day 7'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

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) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 19:06:51

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	03 Nov 2020 02:15:12
User entered 'Day 8'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '04 Nov 2020 12:00'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '05 Nov 2020 11:59'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	03 Nov 2020 02:15:12
User entered 'Day 8'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '04 Nov 2020 12:00'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '05 Nov 2020 11:59'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
Data entry locked.	System	03 Nov 2020 02:15:12
User entered 'Day 8'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:30:47

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 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42

US3952141

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '04 Nov 2020 12:00'	System	03 Nov 2020 02:15:12

US3952141

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:30:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:22:42
User entered '05 Nov 2020 11:59'	System	03 Nov 2020 02:15:12

US3952141

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:31
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	04 Nov 2020 21:06:17

US3952141

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:31
User entered '04 Nov 2020'	Brianne Okunji (b) (4) (b) (4)	04 Nov 2020 21:06:17

US3952141

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:31
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4) (b) (4)	04 Nov 2020 21:06:17

US3952141

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:31
User entered empty.	Brianne Okunji (b) (4) (b) (4)	04 Nov 2020 21:06:17

US3952141

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:34
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:00:45

US3952141

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'I'	System	12 Nov 2020 23:00:45

US3952141

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:49
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:01:26

US3952141

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:49
User entered '12 Nov 2020'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:01:26

US3952141

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:49
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:01:26

US3952141

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:49
User entered empty.	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:01:26

US3952141

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:48:54
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	12 Nov 2020 23:01:34

US3952141

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'I'	System	12 Nov 2020 23:01:34

US3952141

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:00
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	19 Nov 2020 22:10:10

US3952141

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:00
User entered '19 Nov 2020'	Brianne Okunji (b) (4) (b) (4)	19 Nov 2020 22:10:10

US3952141

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:00
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4) (b) (4)	19 Nov 2020 22:10:10

US3952141

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:00
User entered empty.	Brianne Okunji (b) (4) (b) (4)	19 Nov 2020 22:10:10

US3952141

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:19
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	19 Nov 2020 22:10:22

US3952141

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'I'	System	19 Nov 2020 22:10:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:37
User entered 'Yes (Y)'	Nick Bart (b) (4)	02 Dec 2020 15:12:03

US3952141

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:37
User entered '23 Nov 2020'	Nick Bart (b) (4)	02 Dec 2020 15:12:03

US3952141

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:37
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	02 Dec 2020 15:12:03

US3952141

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:30:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'VISIT3'	System	02 Dec 2020 15:12:03

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered 'Yes (Y)'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '23 Nov 2020'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '15:40'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '23 Nov 2020 15:40'	System	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '37.5' C	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered 'Oral (Oral)'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '71'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'bpm'	System	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '14'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'breaths/min'	System	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '139'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'mmHg'	System	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:50:21
User entered '90'	Nick Bart (b) (4)	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'mmHg'	System	02 Dec 2020 15:12:22

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41

US3952141

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:30:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41

US3952141

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:52
User entered 'No (N)'	Nick Bart (b) (4)	02 Dec 2020 15:12:29

US3952141

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:30:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:49:52
User entered empty.	Nick Bart (b) (4)	02 Dec 2020 15:12:29

US3952141

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:51:06
User entered 'Yes (Y)'	Nick Bart (b) (4)	02 Dec 2020 15:12:40

US3952141

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:51:06
User entered '23 Nov 2020'	Nick Bart (b) (4)	02 Dec 2020 15:12:40

US3952141

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:51:06
User entered '15:48'	Nick Bart (b) (4)	02 Dec 2020 15:12:40

US3952141

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:30:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered '23 Nov 2020 15:48'	System	02 Dec 2020 15:12:40

US3952141

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:51:12
User entered 'Yes (Y)'	Nick Bart (b) (4)	02 Dec 2020 15:11:57

US3952141

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'I'	System	02 Dec 2020 15:11:57

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[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 (3bb577645668a992)', Time: '2020-11-30T21:19:53', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '67e51b75-9d54-4f53-99c1-a37276a58ae2'	System	01 Dec 2020 02:20:29
User entered 'No (N)'	System	01 Dec 2020 02:20:29

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Have you been exposed to someone with 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 (3bb577645668a992)', Time: '2020-11-30T21:20:00', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '67e51b75-9d54-4f53-99c1-a37276a58ae2'	System	01 Dec 2020 02:20:29
User entered 'No (N)'	System	01 Dec 2020 02:20:29

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-11-30T21:20:25', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: '67e51b75-9d54-4f53-99c1-a37276a58ae2'	System	01 Dec 2020 02:20:29
User entered '30 Nov 2020 21:20:25'	System	01 Dec 2020 02:20:29

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[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 (3bb577645668a992)', Time: '2020-12-14T19:17:38', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd5cfe7b9-cdcf-4225-b7e8-2e56415a62dc'	System	15 Dec 2020 00:17:49
User entered 'No (N)'	System	15 Dec 2020 00:17:49

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

Have you been exposed to someone with 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 (3bb577645668a992)', Time: '2020-12-14T19:17:23', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd5cfe7b9-cdcf-4225-b7e8-2e56415a62dc'	System	15 Dec 2020 00:17:49
User entered 'No (N)'	System	15 Dec 2020 00:17:49

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bb577645668a992)', Time: '2020-12-14T19:17:47', User OID: 'PatientReportedOutcome (US3952141)', ODM File OID: 'd5cfe7b9-cdcf-4225-b7e8-2e56415a62dc'	System	15 Dec 2020 00:17:49
User entered '14 Dec 2020 19:17:47'	System	15 Dec 2020 00:17:49

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 10:28:26

US3952141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:30:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:28:26
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 10:28:26

US3952141

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:51:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 21:13:20

US3952141

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:51:34
User entered '21 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 21:13:20

US3952141

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:51:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Dec 2020 21:13:20

US3952141

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:51:34
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:13:20

US3952141

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:45:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 18:51:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 21:13:27

US3952141

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:28:41
User entered 'I'	System	21 Dec 2020 21:13:27

US3952141

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:22:35
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	29 Jan 2021 22:42:27

US3952141

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:22:35
User entered '29 Jan 2021'	Brianne Okunji (b) (4) (b) (4)	29 Jan 2021 22:42:27

US3952141

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:22:35
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4) (b) (4)	29 Jan 2021 22:42:27

US3952141

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:22:35
User entered empty.	Brianne Okunji (b) (4) (b) (4)	29 Jan 2021 22:42:27

US3952141

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:24
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:22:40
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	29 Jan 2021 22:42:34

US3952141

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:24
User entered 'I'	System	29 Jan 2021 22:42:34

US3952141

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:21:27
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	25 Feb 2021 19:06:03

US3952141

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:21:27
User entered '25 Feb 2021'	Brianne Okunji (b) (4) (b) (4)	25 Feb 2021 19:06:03

US3952141

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:21:27
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4) (b) (4)	25 Feb 2021 19:06:03

US3952141

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:21:27
User entered empty.	Brianne Okunji (b) (4) (b) (4)	25 Feb 2021 19:06:03

US3952141

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:21:33
User entered 'Yes (Y)'	Brianne Okunji (b) (4) (b) (4)	25 Feb 2021 19:06:11

US3952141

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:00:34
User entered 'I'	System	25 Feb 2021 19:06:11

US3952141

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:59:17
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 19:43:22

US3952141

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:59:17
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 19:43:22

US3952141

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:59:17
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Mar 2021 19:43:22

US3952141

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:30:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:59:17
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:43:22

US3952141

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:28
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:59:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 19:43:28

US3952141

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:30:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:28
User entered 'I'	System	30 Mar 2021 19:43:28

US3952141

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:30:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:55
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:12:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:39
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:14:18

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 21:16:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 21:16:04
Data point term sent to Coder	System	24 Feb 2021 21:15:07
User entered 'vitamin d deficiency'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '15 Jan 2021'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'Not Applicable (NOT APPLICABLE)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'I'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:06:47
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:30:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 21:14:57

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:32:08
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:36
Un-reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:33
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:36:46
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:36:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:36:31
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:36:26
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:35:50
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:35:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:35:29
User entered 'USA-US215-2021-mRNA-1273-P301000006'	System	26 Mar 2021 17:35:22
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 17:35:22

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4)	06 Apr 2021 15:32:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Spinal osteoarthritis, LLT: Lumbar spondylosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:00:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:00:37
Data point term sent to Coder	System	25 Mar 2021 20:59:28
User entered 'worsening of lumbar spondylosis'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:32:15
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 15:32:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:32:11
User entered 'Yes (Y)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:32:17
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:32:19
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:32:22
User entered '04 Feb 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	26 Mar 2021 12:36:51
User entered '4 Feb 2021'	Mimi Van Der Leden	25 Mar 2021 20:58:36
	(b) (4)	

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:32:24
User entered empty.	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:32:26
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:41:15
User closed query 'Per MAR, subject was discharged on 16Mar2021.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:41:12
Query 'Per MAR, subject was discharged on 16Mar2021.' answered with 'updated' (Site from CRA).	Mimi Van Der Leden (b) (4)	08 Apr 2021 17:13:09
User entered '10 Mar 2021' reason for change: New Information	Mimi Van Der Leden (b) (4)	08 Apr 2021 17:12:53
User opened query 'Per MAR, subject was discharged on 16Mar2021.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:38:24
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 12:36:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Mar 2021 12:36:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Mar 2021 20:58:36
User entered '18 Mar 2021'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:27
User entered empty.	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:30
User entered 'Yes (Y)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:26
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:28
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:29
User entered 'I'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:59
User entered '10 Mar 2021'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:45:15
User closed query 'Per MAR, subject was discharged on 16Mar2021.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:41:21
Query 'Per MAR, subject was discharged on 16Mar2021.' answered with 'correct' (Site from CRA).	Mimi Van Der Leden (b) (4)	08 Apr 2021 17:13:21
User entered '16 Mar 2021' reason for change: New Information	Mimi Van Der Leden (b) (4)	08 Apr 2021 17:12:53
User opened query 'Per MAR, subject was discharged on 16Mar2021.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:38:18
User entered '18 Mar 2021'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:32
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 15:38:39
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:38:36
User entered 'No (N)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	06 Apr 2021 15:40:04
User entered empty.	[REDACTED] Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:40:05
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:40:07
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:40:09
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:38:41
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:39:08
User entered 'Not Related (NOT RELATED)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:39:17
User entered 'Not Applicable (NOT APPLICABLE)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

None

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:39:38
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 20:13:17
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Mar 2021 12:39:03
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4)	26 Mar 2021 12:39:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Mar 2021 20:58:36
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:39:39
User entered '0'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:39:41
User entered '1' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 20:13:17
User entered '0'	Mimi Van Der Leden	25 Mar 2021 20:58:36
	(b) (4)	

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:39:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nick Bart (b) (4)	26 Mar 2021 12:36:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:39:45
User entered empty.	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:21:50
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:01:41
' (Site from Safety). Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	Atanas Filev (b) (4) (b) (4)	13 Apr 2021 01:06:22
' answered with 'Requested records sent to Safety_Moderna@iqvia.com' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 23:02:18
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:06:47
User closed query 'Please consider changing SPING to SPINE in the second to last line of the final narrative.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:07:38
Query 'Please consider changing SPING to SPINE in the second to last line of the final narrative.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 17:03:20

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HOSPITALIZED 10MAR2021 FOR LUMBAR 4-5 SPINAL FUSION BECAUSE OF WORSENING LUMBAR SPONDYLOSIS. UNEVENTFUL COURSE. DISCHARGED 18MAR2021 TO REHAB. CURRENTLY IN REHAB. COVID NEGATIVE X 2 TESTS IN HOSPITAL. FURTHER DETAILS UPON RECEIPT OF MEDICAL RECORDS. UPON RECEIPT AND REVIEW OF MEDICAL RECORDS CLARIFY HOSPITAL DISCHARGE DATE. ADMITTED 10MAR2021 DISCHARGED TO ACUTE REHAB ON 16MAR2021. SUBJECT WAS ADMITTED TO HOSPITAL FOR WORSENING LUMBAR SPONDYLOSIS WITH SIGNIFICANT BACK PAIN WITH RADICULOPATHY. SHE UNDERWENT A L5-S1 TRANSFORAMINAL LUMBAR INTERBODY FUSION (SPINAL FUSION) ON 10MAR2021. SHE HAD NO POST OPERATIVE COMPLICATIONS AND TOLERATED PHYSICAL THERAPY WELL. SHE TESTED NEG FOR COVID ON 15MAR2021. HAD LUMBAR SPINE CT ON 11MAR2021 AND 13MAR2021 POST OPERATIVELY REVEALING STABLE POST FUSION. HAD MRI OF SPINE 15MAR2021 REVEALING NO CAUDA EQUINE COMPRESSION AND EXPECTED L5-S1 POST OP CHANGES. WAS DISCHARGED TO ACUTE REHAB ON 16MAR2021.' reason for change: New Information	Nick Bart (b) (4)	09 Apr 2021 17:03:08
User opened query 'Please consider changing SPING to SPINE in the second to last line of the final narrative.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:43:08

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HOSPITALIZED 10MAR2021 FOR LUMBAR 4-5 SPINAL FUSION BECAUSE OF WORSENING LUMBAR SPONDYLOSIS. UNEVENTFUL COURSE. DISCHARGED 18MAR2021 TO REHAB. CURRENTLY IN REHAB. COVID NEGATIVE X 2 TESTS IN HOSPITAL. FURTHER DETAILS UPON RECEIPT OF MEDICAL RECORDS. Upon receipt and review of medical records clarify hospital discharge date. Admitted 10Mar2021 Discharged to acute rehab on 16Mar2021. Subject was admitted to hospital for worsening lumbar spondylosis with significant back pain with radiculopathy. She underwent a L5-S1 transforaminal lumbar interbody fusion (spinal fusion) on 10Mar2021. She had no post operative complications and tolerated physical therapy well. She tested neg for covid on 15Mar2021. Had lumbar spine CT on 11Mar2021 and 13Mar2021 post operatively revealing stable post fusion. Had MRI of sping 15Mar2021 revealing no cauda equine compression and expected L5-S1 post op changes. Was discharged to acute rehab on 16Mar2021.' reason for change: New Information	Mimi Van Der Leden (b) (4)	08 Apr 2021 17:12:53
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:42:58
User closed query 'PV Query: Kindly confirm if the subject had a history of lumbar spondylosis, please provide further details. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:42:52
User closed query 'PV Query: Event reported as worsening of lumbar spondylosis. Kindly confirm when the subject was diagnosed with lumbar spondylosis as it is not included in medical history and any previous hospitalizations. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:42:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

1659 of 2216

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Event reported as worsening of lumbar spondylosis. Kindly confirm when the subject was diagnosed with lumbar spondylosis as it is not included in medical history and any previous hospitalizations. ' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:12:38
Query 'PV Query: Kindly confirm if the subject had a history of lumbar spondylosis, please provide further details. ' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:12:18
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:10:08
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	05 Apr 2021 13:09:31
' (Site from Safety).		
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:09:14
User opened query 'PV Query: Kindly confirm if the subject had a history of lumbar spondylosis, please provide further details. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:09:01

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Event reported as worsening of lumbar spondylosis. Kindly confirm when the subject was diagnosed with lumbar spondylosis as it is not included in medical history and any previous hospitalizations. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:08:52
User entered 'Subject hospitalized 10Mar2021 for lumbar 4-5 spinal fusion because of worsening lumbar spondylosis. Uneventful course. Discharged 18Mar2021 to rehab. Currently in rehab. Covid negative x 2 tests in hospital.	Mimi Van Der Leden (b) (4)	25 Mar 2021 20:58:36

Further details upon receipt of medical records.'

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 20:58:36

US3952141

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:30:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 20:58:36

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:30:47

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:55
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
User closed query 'Source indicates con med "Vitamin D" with start date 23JAN2021. Please confirm and enter in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:13:55
Query 'Source indicates con med "Vitamin D" with start date 23JAN2021. Please confirm and enter in EDC.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	03 Mar 2021 19:41:19
User opened query 'Source indicates con med "Vitamin D" with start date 23JAN2021. Please confirm and enter in EDC.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:39:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:25:06
User closed query 'Per source page 5 of Day0/1 visit from 23Sep20, patient had vaccine but was entered. Please reconcile and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 07:21:56
Query 'Per source page 5 of Day0/1 visit from 23Sep20, patient had vaccine but was entered. Please reconcile and update if necessary.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	29 Dec 2020 18:51:20
User opened query 'Per source page 5 of Day0/1 visit from 23Sep20, patient had vaccine but was entered. Please reconcile and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 19:12:38
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:13:00

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	24 Feb 2021 20:30:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:52:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:52:19
Data point term sent to Coder Coding entries removed.	System Nick Bart (b) (4) [REDACTED]	29 Dec 2020 18:51:41 29 Dec 2020 18:51:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:14:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:14:53
Data point term sent to Coder User entered 'zyrtec'	System Nick Bart (b) (4) [REDACTED]	25 Sep 2020 14:13:42 25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:30:46
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:40:36
User closed query 'Source indicates "allergies" for this con med. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:40:32
Query 'Source indicates "allergies" for this con med. Please confirm and update as needed.' answered with 'Source updated' (Site from CRA).	Nick Bart (b) (4)	03 Mar 2021 19:40:31
User opened query 'Source indicates "allergies" for this con med. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:33:39
User closed query 'Per DM CLR: Please update the indication to reflect the location or type of ALLERGIES. Review and reconcile with MH entry so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:01:58
Query 'Per DM CLR: Please update the indication to reflect the location or type of ALLERGIES. Review and reconcile with MH entry so there is an appropriate match.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 18:51:11
User entered 'seasonal ALLERGIES' reason for change: New Information	Nick Bart (b) (4)	29 Dec 2020 18:51:06
User opened query 'Per DM CLR: Please update the indication to reflect the location or type of ALLERGIES. Review and reconcile with MH entry so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:21:51
User entered 'allergies'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:33:53
User entered '10'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:33:55
User entered 'mg (mg)'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:03
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:06
User entered 'once daily (QD)'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:14
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:16
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:19
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:22
User entered 'un Feb 2019'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:24
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:27
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:30
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:34:34
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 14:13:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	24 Feb 2021 20:35:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:15:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 14:15:55
Data point term sent to Coder	System	25 Sep 2020 14:14:44
User entered 'aleve'	Nick Bart (b) (4) [REDACTED]	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:35:49
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:36:05
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:02:10
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'MH updated' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:55:20
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:23:28
User entered 'headaches'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:36:10
User entered 'I'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:36:15
User entered 'tablet (TABLET)'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:36:20
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:36:23
User entered 'as needed (PRN)'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:37:43
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:37:44
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:37:51
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:37:54
User entered 'un Aug 2020'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:37:59
User entered '0'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:38:03
User entered 'Yes (Y)'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:38:06
User entered empty.	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:38:08
User entered 'No (N)'	Nick Bart (b) (4)	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 14:13:50

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:53:20
Data point term sent to Coder	System	29 Dec 2020 18:52:42
User entered 'influenza vaccine'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Yes (Y)'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'influenza prevention'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '0.5'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'mL (mL)'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'once (ONCE)'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'un Sep 2019'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '0'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'un Sep 2019'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	Nick Bart (b) (4)	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User entered empty.	System	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User entered empty.	System	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:45:33
User entered empty.	System	29 Dec 2020 18:52:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 20:03:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 21:17:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 21:17:01
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 21:16:15
User entered 'vitamin d'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:21
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:22
User entered 'vitamin d deficiency'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:24
User entered '1000'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:25
User entered 'IU (IU)'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:27
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:28
User entered 'once daily (QD)'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:30
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:31
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:33
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:08:09
User entered '23 Jan 2021'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:08:07
User entered '0'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:08:05
User entered 'Yes (Y)'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:35
User entered empty.	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:38
User entered 'No (N)'	Nick Bart (b) (4)	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 21:15:47

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	06 Apr 2021 16:43:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4) [REDACTED]	05 Apr 2021 14:24:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4) [REDACTED]	05 Apr 2021 14:24:27
Data point term sent to Coder	System	05 Apr 2021 13:47:38
User entered 'GABAPENTIN'	(b) (4), (b) (6) [REDACTED]	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:43:07
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:08
User entered 'WORSENING LUMBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:10
User entered '300'		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:11
User entered 'mg (mg)'		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:13
User entered empty.		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:15
User entered 'as needed (PRN)'		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:16
User entered empty.		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:43:19
User entered empty.		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:43:33
User entered '04 Feb 2021'		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:03:53
User entered '0'		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:00
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 17:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 17:01:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 17:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 17:01:21
DataPoint Un-verified.	Nick Bart (b) (4)	09 Apr 2021 17:01:21
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 17:01:21
User closed query 'Per ConMeds, still ongoing.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:56:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:22
Query 'Per ConMeds, still ongoing.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:14:22
User opened query 'Per ConMeds, still ongoing.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:50:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:49:13
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:48:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:57:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:06:57
User closed query 'Per MAR, subject continued Gabapentin until 16Mar21. Please confirm and reconcile.' (Site from CRA).		09 Apr 2021 17:06:53
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 17:01:21
Query 'Per MAR, subject continued Gabapentin until 16Mar21. Please confirm and reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:14:25
User entered '16 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:14:16
User opened query 'Per MAR, subject continued Gabapentin until 16Mar21. Please confirm and reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:48:44
User entered '14 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:57:49
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 06 Apr 2021 16:48:45
User entered 'No (N)'		05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:46:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 18:54:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:40:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:40:25
Data point term sent to Coder	System	05 Apr 2021 13:56:48
User entered 'OXYCODONE'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:32
User entered 'No (N)'		05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:31
User entered 'WORSENING LUBAR SPONDYLOSIS'		05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:37
User entered '20'		05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:39
User entered 'mg (mg)'		05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:42
User entered empty.		05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	06 Apr 2021 18:54:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:46
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:50
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 16:43:03
User closed query 'Per MAR, subject began tx at 11Mar21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:43:01
Query 'Per MAR, subject began tx at 11Mar21. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:14:57
User entered '11 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:14:51
User opened query 'Per MAR, subject began tx at 11Mar21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:54:19
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:23
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:25
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:54:26
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:56:15

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:35:31
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)	05 Apr 2021 14:08:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:08:20
Data point term sent to Coder	System	05 Apr 2021 13:59:52
User entered 'ACETAMINOPHEN '	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:35:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:59:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 13:59:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:59:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:59:40
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:35:43
User entered 'WORSENING LUBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:43:38
DataPoint Un-verified.	Nick Bart (b) (4)	09 Apr 2021 16:15:21
User entered '650' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:15:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:35:49
User entered '625'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:35:50
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:35:53
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:28
User entered 'other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:30
User entered 'Q6H'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:36:36
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 16:43:36
User closed query 'Per MAR, subject started 650mg of Tylenol on 11Mar21. Please confirm and reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:43:34
Query 'Per MAR, subject started 650mg of Tylenol on 11Mar21. Please confirm and reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:15:24
User entered '11 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:15:21
User opened query 'Per MAR, subject started 650mg of Tylenol on 11Mar21. Please confirm and reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:37:15
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:37:31
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:44
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:46
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:59:40

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:23:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:27:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:27:25
Data point term sent to Coder	System	05 Apr 2021 14:00:55
User entered 'METHOCARBAMOL'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:23:52
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:23:54
User entered 'WORSENING LUBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:23:56
User entered '1000'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:23:59
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:24:01
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:24:03
User entered 'other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:45:23
User closed query 'Subject received drug less than QID several days, please consider PRN.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:45:21
Query 'Subject received drug less than QID several days, please consider PRN.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:16:49
User entered 'PRN' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:16:43
User opened query 'Subject received drug less than QID several days, please consider PRN.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:31:07
User entered 'QID'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:31:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:31:55
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:31:57
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:31:58
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:32:01
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:32:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:00:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:07:15
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 Apr 2021 08:07:15
User signature succeeded.	Mimi Van Der Leden (b) (4)	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:45:58
User closed query 'Add percentage to the name of medication.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:45:56
Data point term sent to Coder	System	09 Apr 2021 16:18:11
User entered 'LIDOCAINE PATCH 4%' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:17:40
Query 'Add percentage to the name of medication.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:17:17
Coding entries removed.	Nick Bart (b) (4)	09 Apr 2021 16:17:14
User entered 'LIDOCAINE PATCH 5%' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:17:14
User opened query 'Add percentage to the name of medication.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:19:14
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 18:19:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:23

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANESTHETICS FOR TOPICAL USE, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:31:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:31:27
Data point term sent to Coder	System	05 Apr 2021 14:01:55
User entered 'LIDOCAINE PATCH'	(b) (4), (b) (6) (b) (4)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:27
User entered 'WORSENING LUBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
User closed query 'Per MAR, site administered 1 patch. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:47:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:47:15
Query 'Per MAR, site administered 1 patch. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:18:04
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:17:40
User opened query 'Per MAR, site administered 1 patch. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:19:50
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 18:19:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:29
User entered '4'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:31
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
User closed query 'Please use dose/inches for patch.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:47:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:47:46
Query 'Please use dose/inches for patch.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:18:01
User entered 'patch' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:17:40
User opened query 'Please use dose/inches for patch.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:20:56
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 18:19:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:32
User entered '%'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:35
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:37
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:39
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:44
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:47
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:48
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:23:21
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:23:23
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User entered empty.	System	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User entered empty.	System	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:53
User entered empty.	System	05 Apr 2021 14:01:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:55:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:39:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:39:22
Data point term sent to Coder	System	05 Apr 2021 14:03:57
User entered 'NOVOLOG'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:02
User entered 'POST OP BG CONTROL'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:04
User entered '2'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:05
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:07
User entered 'UNITS'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:56:11
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	05 Apr 2021 14:04:18
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:04:18
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). User entered 'once (ONCE)'	System	05 Apr 2021 14:03:34
	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:17
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:56:14
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:56:32
User closed query 'Per MAR, subject received on 15Mar21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:56:31
Query 'Per MAR, subject received on 15Mar21. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:18:54
User entered '15 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:18:17
User opened query 'Per MAR, subject received on 15Mar21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:57:46
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:57:49
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:57:51
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:56:36
User closed query 'Per MAR, subject received only on 15Mar21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:56:34
Query 'Per MAR, subject received only on 15Mar21. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:18:57
User entered '15 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:18:51
User opened query 'Per MAR, subject received only on 15Mar21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:58:13
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:58:15
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User entered '1'	System	05 Apr 2021 14:04:18
User entered empty.	System	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User entered '1'	System	05 Apr 2021 14:04:18
User entered empty.	System	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:01:59
User entered '804 (804)'	System	05 Apr 2021 14:04:18
User entered empty.	System	05 Apr 2021 14:03:34

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6) [REDACTED]	09 Apr 2021 18:10:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:14:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:14:16
Data point term sent to Coder	System	05 Apr 2021 14:09:03
User entered 'ALBUTEROL MDI'	(b) (4), (b) (6) [REDACTED]	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '1.25/3'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'mg/mL'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 14:08:03

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:08:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFAZOLIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:26:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:26:53
Data point term sent to Coder	System	05 Apr 2021 14:24:27
Data point term sent to Coder	System	05 Apr 2021 14:19:21
User closed query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	System	05 Apr 2021 14:18:38
Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:18:38
User entered 'Cefazolin (Ancef)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:18:32
User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:17:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

1865 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Apr 2021 14:15:09
User entered 'ANCEF'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:31
User entered 'PREVENTATIVE ANTIBIOTIC'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:33
User entered '2/50'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:35
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:37
User entered 'g/mL'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:38
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:40
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:41
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:23:26
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:44
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:08:46
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:15:53
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:15:55
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:15:57
User entered '15 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:15:58
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User entered '2'	System	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User entered '1'	System	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:31
User entered '804 (804)'	System	05 Apr 2021 14:14:41

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:09:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:09:59
User signature succeeded.	Mimi Van Der Leden (b) (4)	09 Apr 2021 20:18:31
Data point term sent to Coder	System	09 Apr 2021 16:20:15
Coding entries removed.	Nick Bart (b) (4)	09 Apr 2021 16:19:24
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:17:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:17:00
Data point term sent to Coder	System	05 Apr 2021 14:24:26
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 14:23:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:19:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:19:21
Data point term sent to Coder	System	05 Apr 2021 14:16:12
User entered 'diphenhydramine'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

1884 of 2216

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:32
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:34
User entered 'seasonal allergies'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:37
User entered '25/0.5'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:39
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:42
User entered 'mg/mL'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:43
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:52:50
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:36:00
User closed query 'Per MAR on 15Mar21, injection intramuscular. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:35:58
Query 'Per MAR on 15Mar21, injection intramuscular. Please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:19:29
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:19:24
User opened query 'Per MAR on 15Mar21, injection intramuscular. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:53:20
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:23:35
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:54:04
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:54:06
User entered '15 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:54:08
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:54:10
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:54:11
User entered '15 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:55:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User entered empty.	System	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User entered empty.	System	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:53
User entered empty.	System	05 Apr 2021 14:16:06

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:11:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC, PRODUCTSYNONYM: FLEET ENEMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:25:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:25:30
Data point term sent to Coder	System	05 Apr 2021 14:17:18
User entered 'fleet enema'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:24
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:11:26
User entered 'constipation'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:11:28
User entered '133'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:29
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:31
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:33
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:35
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:37
User entered 'Rectal (RECTAL)'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:39
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:42
User entered '13 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:44
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:47
User entered '13 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:11:48
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User entered empty.	System	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User entered empty.	System	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:02:58
User entered empty.	System	05 Apr 2021 14:16:51

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:01:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:19:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:19:20
Data point term sent to Coder	System	05 Apr 2021 14:18:20
User entered 'magnesium citrate'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:38
User entered 'constipation'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:43
User entered '148'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:45
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:47
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:50
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:55
User entered '12 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:57
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:58
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:01:59
User entered '12 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:02:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User entered empty.	System	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User entered empty.	System	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:12
User entered empty.	System	05 Apr 2021 14:17:45

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:23:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:22:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:22:21
Data point term sent to Coder	System	05 Apr 2021 14:20:22
User entered 'cyclobenzaprine'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:52
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:23:54
User entered 'WORSENING LUBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:56
User entered '10'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:23:58
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:00
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:01
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:24
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:27
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:29
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:30
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:24:32
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:34
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:24:35
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User entered '1'	System	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User entered '1'	System	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:30
User entered '804 (804)'	System	05 Apr 2021 14:19:42

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:44
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANESTHETICS FOR TOPICAL USE, PRODUCT: BENZOCAINE;MENTHOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:23:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:23:26
Data point term sent to Coder	System	05 Apr 2021 14:21:23
User entered 'benzocaine menthol lozenge'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:21:47
User entered 'topical anesthesia'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:21:48
User entered '15/3.6'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:49
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:47
User entered 'mg/mg'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:50
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:52
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:26:55
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:56
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:26:58
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:26:59
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:27:01
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:27:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User entered empty.	System	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User entered empty.	System	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:34
User entered empty.	System	05 Apr 2021 14:21:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:18:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:23:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:23:20
Data point term sent to Coder	System	05 Apr 2021 14:23:25
User entered 'dialaudid'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:39
User entered 'POST OP PAIN'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:40
User entered '0.5/0.5'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:42
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:43
User entered 'MG/ML'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:18:45
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:47
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:57
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:23:07
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:18:59
User entered 'INJECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:23:07
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:00
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:02
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:05
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:07
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User entered empty.	System	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User entered empty.	System	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:40
User entered empty.	System	05 Apr 2021 14:22:32

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:49:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:49:38
Data point term sent to Coder	System	05 Apr 2021 14:25:28
User entered 'ZOFRAN'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:21
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:24:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:24:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:24:44
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:24:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:24
User entered 'NAUSEA'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:25
User entered '4/2'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:28
User entered 'MG/ML'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:30
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:32
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:33
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:36
User entered 'IV INJECTION'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:39
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:41
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:20:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:20:52
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:20:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User entered empty.	System	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User entered empty.	System	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:03:45
User entered empty.	System	05 Apr 2021 14:24:33

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:34:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:40:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:40:25
Data point term sent to Coder	System	05 Apr 2021 14:26:29
User entered 'OXYCODONE'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:34:49
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:34:58
User entered 'WORSENING LUBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:34:59
User entered '10'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:35:05
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:35:06
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:35:08
User entered 'other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:35:49
User entered 'Q4HR PRN'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:35:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:35:52
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:55:53
User closed query 'Per MAR, start date is on 10Mar21.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:55:51
Query 'Per MAR, start date is on 10Mar21.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:22:54
User entered '10 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:22:50
User opened query 'Per MAR, start date is on 10Mar21.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:36:05
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:36:09
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:42:02
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:36:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:36:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:42:03
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:42:05
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:25:28

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:24:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:40:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:40:25
Data point term sent to Coder	System	05 Apr 2021 14:26:29
User entered 'OXYCODONE'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:24:34
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:24:36
User entered 'WORSENING LUBAR SPONDYLOSIS'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:24:37
User entered '15'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:24:39
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:43
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:45
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:58
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:59
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:33:55
User closed query 'Per MAR, Oxy 15mg started on 12Mar21, please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:33:54
Query 'Per MAR, Oxy 15mg started on 12Mar21, please reconcile.' answered with 'updated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:23:14
User entered '12 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:23:10
User opened query 'Per MAR, Oxy 15mg started on 12Mar21, please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:28:22
User entered '11 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:28:24
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:28:26
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:45:04
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:42:24
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User entered empty.	System	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User entered empty.	System	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:25
User entered empty.	System	05 Apr 2021 14:26:11

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:07:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 14:28:28
	(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 Apr 2021 14:28:28
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 14:27:29
User entered 'DOCUSATE'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:07:07
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:27:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:27:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:27:15
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:27:05
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:07:09
User entered 'CONSTIPATION'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:07:10
User entered '100'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:07:12
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:07:13
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4)	06 Apr 2021 17:12:39
	(b) (4), (b) (6)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:44
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:46
User entered '10 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:49
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:52
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:53
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 14:27:05

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:02:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:29:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:29:20
Data point term sent to Coder	System	05 Apr 2021 14:28:31
User entered 'LACTULOSE'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:02:56
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:02:57
User entered 'CONSTIPATION'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:02:59
User entered '10/5'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:01
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:02
User entered 'MG/ML'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:06
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:09
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:11
User entered '12 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:06:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
User closed query 'Lactulose given once on 12Mar21, then again on 15Mar21 but not in between. Please add stop date as 12Mar21 and create new page for Lactulose starting on 15Mar21 and end 15Mar21.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:33:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:33:31
Query 'Lactulose given once on 12Mar21, then again on 15Mar21 but not in between. Please add stop date as 12Mar21 and create new page for Lactulose starting on 15Mar21 and end 15Mar21.' answered with 'separated' (Site from CRA).	Nick Bart (b) (4)	09 Apr 2021 16:20:56
User entered '12 Mar 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	09 Apr 2021 16:20:51
User opened query 'Lactulose given once on 12Mar21, then again on 15Mar21 but not in between. Please add stop date as 12Mar21 and create new page for Lactulose starting on 15Mar21 and end 15Mar21.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 19:07:52
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:08:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User entered '1'	System	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User entered '1'	System	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:30
User entered '804 (804)'	System	05 Apr 2021 14:28:09

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:23:44
Data point term sent to Coder	System	09 Apr 2021 16:22:18
User entered 'lactulose'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'constipation'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '10/15'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Other (OTHER)'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'g/ml'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'once daily (QD)'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered empty.	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '15 Mar 2021'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '0'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered '15 Mar 2021'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:31
User entered 'No (N)'	Nick Bart (b) (4)	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User entered '1'	System	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User entered '1'	System	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:30:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User entered '804 (804)'	System	09 Apr 2021 16:21:58

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:30:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:17:55
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
User closed query 'Per ETRTR: According to SAE page "Worsening of Lumbar Spondylosis", a Procedure was performed for SAE (SPINAL FUSION), but the same is missing in this folder. Please 1) add Concomitant Procedure details for SAE and 2) within SAE page, tick on Concomitant Procedures Action taken, thanks.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:16
	(b) (4), (b) (6)	06 Apr 2021 17:13:13
Query 'Per ETRTR: According to SAE page "Worsening of Lumbar Spondylosis", a Procedure was performed for SAE (SPINAL FUSION), but the same is missing in this folder. Please 1) add Concomitant Procedure details for SAE and 2) within SAE page, tick on Concomitant Procedures Action taken, thanks.' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 20:13:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 20:13:44
User opened query 'Per ETRTR: According to SAE page "Worsening of Lumbar Spondylosis", a Procedure was performed for SAE (SPINAL FUSION), but the same is missing in this folder. Please 1) add Concomitant Procedure details for SAE and 2) within SAE page, tick on Concomitant Procedures Action taken, thanks.' (Site from CRA). User entered 'No (N)'	(b) (4), (b) (6) Nick Bart (b) (4)	30 Mar 2021 17:23:53 11 Mar 2021 20:01:24

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:30:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	06 Apr 2021 17:13:29
User entered '10 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 20:18:12

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:30:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 06 Apr 2021 17:13:29
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.'	(b) (4), (b) (6)	06 Apr 2021 15:00:21
(Site from DM).		
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.'	(b) (4), (b) (6)	05 Apr 2021 19:07:42
answered with 'Updated.' (Site from DM).		
User entered 'LUMBAR 4-5 SPINAL FUSION [LUMBAR SPONDYLOLISTHESIS, L5-S1 STENOSIS, RADICULOPATHY, AND BACK PAIN]' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:06:54
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.'	(b) (4), (b) (6)	05 Apr 2021 00:08:10
(Site from DM).		
User entered 'Lumbar Spondylolisthesis, L5-S1 stenosis, radiculopathy, and back pain.'	(b) (4), (b) (6)	30 Mar 2021 20:18:12

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:29
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Mar 2021 20:18:12

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:30:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:18:12

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:30:47

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered '11 Mar 2021'	(b) (4), (b) (6)	09 Apr 2021 18:19:17

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:30:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered 'Lumbar Spine CT w/o contrast for lumbar spondylosis'		09 Apr 2021 18:19:17

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	09 Apr 2021 18:19:17

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:30:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:11
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:17

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:30:47

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:16
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered '13 Mar 2021'	(b) (4), (b) (6)	09 Apr 2021 18:19:43

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:30:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:16
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered 'LUMBAR SPINE CT W/O CONTRAST FOR LUMBAR SPONDYLOSIS'	(b) (4), (b) (6)	09 Apr 2021 18:19:43

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:16
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	09 Apr 2021 18:19:43

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:30:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:16
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:43

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:30:47

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered '15 Mar 2021'	(b) (4), (b) (6)	09 Apr 2021 18:20:16

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:30:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered 'MRI Spine w/o contrast for LUMBAR SPONDYLOSIS'	(b) (4), (b) (6)	09 Apr 2021 18:20:16

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:30:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	09 Apr 2021 18:20:16

US3952141

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:30:47

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:09:19
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:20:50
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:20:16

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'USA-US215-2021-MRNA-1273-P301000006'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Mimi'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Van Der Leden'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '15201 Shady Grove Dr'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Rockville'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '20850'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'US'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:42:41
User entered '4'	System	09 Apr 2021 12:57:09
User entered '3'	System	06 Apr 2021 14:43:21
User entered '2'	System	31 Mar 2021 15:08:08
User entered '1'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'USA-US215-2021-MRNA-1273-P301000006'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	06 Apr 2021 15:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Mimi'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Van Der Leden'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '15201 Shady Grove Dr'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Rockville'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '20850'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'US'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:42:41
User entered '4'	System	09 Apr 2021 12:57:09
User entered '3'	System	06 Apr 2021 14:43:21
User entered '2'	System	31 Mar 2021 15:08:08
User entered '1'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:30:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
User entered '26/Mar/2021 13:37'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:30:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'USA-US215-2021-MRNA-1273-P301000006'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	06 Apr 2021 15:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	06 Apr 2021 15:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Mimi'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Van Der Leden'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '15201 Shady Grove Dr'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Rockville'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '20850'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'US'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:42:41
User entered '4'	System	09 Apr 2021 12:57:09
User entered '3'	System	06 Apr 2021 14:43:21
User entered '2'	System	31 Mar 2021 15:08:08
User entered '1'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:30:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
User entered '31/Mar/2021 11:08'	System	31 Mar 2021 15:08:08

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:30:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 12:57:15
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:14:29
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 15:08:08

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'USA-US215-2021-MRNA-1273-P301000006'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	06 Apr 2021 15:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Mimi'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Van Der Leden'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '15201 Shady Grove Dr'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Rockville'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '20850'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'US'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:42:41
User entered '4'	System	09 Apr 2021 12:57:09
User entered '3'	System	06 Apr 2021 14:43:21
User entered '2'	System	31 Mar 2021 15:08:08
User entered '1'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:30:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:14:29
User entered '06/Apr/2021 10:43'	System	06 Apr 2021 14:43:21

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:30:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 12:57:15
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:43:21

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'USA-US215-2021-MRNA-1273-P301000006'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Mimi'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Van Der Leden'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '15201 Shady Grove Dr'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Rockville'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '20850'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'US'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:42:41
User entered '4'	System	09 Apr 2021 12:57:09
User entered '3'	System	06 Apr 2021 14:43:21
User entered '2'	System	31 Mar 2021 15:08:08
User entered '1'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:30:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:50
User entered '09/Apr/2021 08:57'	System	09 Apr 2021 12:57:09

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:30:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:07:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 12:57:15
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 12:57:09

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'USA-US215-2021-MRNA-1273-P301000006'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Yes (Y)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'No (N)'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Mimi'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Van Der Leden'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '15201 Shady Grove Dr'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered 'Rockville'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 17:37:14
User entered '20850'	System	26 Mar 2021 17:35:22

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:14:29
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:07:53
User entered 'US'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:30:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:42:41
User entered '4'	System	09 Apr 2021 12:57:09
User entered '3'	System	06 Apr 2021 14:43:21
User entered '2'	System	31 Mar 2021 15:08:08
User entered '1'	System	26 Mar 2021 17:37:29

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:30:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:03:48
User entered '12/Apr/2021 09:42'	System	12 Apr 2021 13:42:41

US3952141

Folder: SAE USA-US215-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:30:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:03:48
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 13:42:41