

US3712013 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

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US3712013

Form: Participant Creation

Data signed: (b) (4) 04 Apr 2021 23:52:04

Generated On: 10 Jun 2021 09:20:39

Participant ID

US3712013

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

US3712013

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 AUG 2020

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

Folder OID SCRN

US3712013

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3712013

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Date of Informed Consent (*dd MMM yyyy*) 27 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3712013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Start Year (derived)	1958
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712013

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712013

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Condition	PREMATURE VENTRICULAR COMPLEXES
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712013

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 27 AUG 2020

Time of assessment (00:00-23:59) 13:10 (24 HR)

Vital Signs Date and Time (derived) 27 AUG 2020 13:10

Height (xxx.x) 162.8 cm

Weight (xxx.x) 90.9 kg

BMI (xxx.x) 34.29692 kg/m²

BMI units KG/M2

Temperature (xxx.x) 36.7 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 65 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 117 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 80 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

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

RESTAURANTS, AND GROCERY STORES

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:58:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 SEP 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 190215

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Height	162.8 cm
Weight	90.7 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Height	162.8 cm
Weight	90.7 kg
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 (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:17 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:17
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Height	162.8 cm
Weight	90.7 kg
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 (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:43 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 12:43
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 12:08 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 12:08

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	08 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:33 (24 HR)
Collection date and time (derived)	08 SEP 2020 10:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Collection date (<i>dd MMM yyyy</i>)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:36	08 SEP 2020 11:36
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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 98.4 °F

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

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

PC Time Stamp 08 SEP 2020 12:42

PC Open Date & Time 08 SEP 2020 12:28

PC Close Date & Time 08 SEP 2020 14:58

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp 08 SEP 2020 17:34
PC Open Date & Time 08 SEP 2020 15:53
PC Close Date & Time 09 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 18:56
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 19:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 19:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 19:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 19:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 18:25
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	08 SEP 2020 12:43
PC Open Date & Time	08 SEP 2020 12:28
PC Close Date & Time	08 SEP 2020 14:58

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 17:34

PC Open Date & Time

08 SEP 2020 15:53

PC Close Date & Time

09 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 SEP 2020 18:57
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	10 SEP 2020 19:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 SEP 2020 19:02

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	12 SEP 2020 19:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	13 SEP 2020 19:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	14 SEP 2020 18:25
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

No
Yes

PC Time stamp	08 SEP 2020 12:43
PC Open Date & Time	08 SEP 2020 12:28
PC Close Date & Time	08 SEP 2020 14:58

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

No
Yes

PC Time stamp	08 SEP 2020 17:35
PC Open Date & Time	08 SEP 2020 15:53
PC Close Date & Time	09 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 18:57
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 19:59
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	11 SEP 2020 19:03
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 19:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 19:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 18:26
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3712013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

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 (<i>dd MMM yyyy</i>)	05 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 09:05
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

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 (<i>dd MMM yyyy</i>)	05 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 11:05
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3712013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

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) 05 OCT 2020

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 05 OCT 2020 10:33

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

US3712013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 OCT 2020

Collection time (*00:00-23:59*) 09:51 (24 HR)

Collection date and time (derived) 05 OCT 2020 09:51

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Collection date (<i>dd MMM yyyy</i>)			05 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	09:57	05 OCT 2020 09:57
Nasopharyngeal Swab 2	No		

US3712013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp 05 OCT 2020 11:14

PC Open Date & Time 05 OCT 2020 10:53

PC Close Date & Time 05 OCT 2020 13:23

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp 05 OCT 2020 22:04
PC Open Date & Time 05 OCT 2020 14:18
PC Close Date & Time 06 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 OCT 2020 17:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 OCT 2020 17:04
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 OCT 2020 17:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 OCT 2020 15:34
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 OCT 2020 17:03
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 OCT 2020 17:23
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

05 OCT 2020 11:14

PC Open Date & Time

05 OCT 2020 10:53

PC Close Date & Time

05 OCT 2020 13:23

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

05 OCT 2020 22:04

PC Open Date & Time

05 OCT 2020 14:18

PC Close Date & Time

06 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	06 OCT 2020 17:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	07 OCT 2020 17:04
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	08 OCT 2020 17:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 OCT 2020 15:34
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	10 OCT 2020 17:03
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 OCT 2020 17:24

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

No
Yes

PC Time stamp	05 OCT 2020 11:15
PC Open Date & Time	05 OCT 2020 10:53
PC Close Date & Time	05 OCT 2020 13:23

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

No
Yes

PC Time stamp	05 OCT 2020 22:04
PC Open Date & Time	05 OCT 2020 14:18
PC Close Date & Time	06 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	06 OCT 2020 17:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	07 OCT 2020 17:05
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 17:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 15:35
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 17:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 03 NOV 2020

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

Folder OID VISIT3

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

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.

US3712013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	03 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:27 (24 HR)
Collection date and time (derived)	03 NOV 2020 10:27

US3712013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:58:43

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 09:34:32
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 NOV 2020 08:05:16
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 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	22 NOV 2020 22:01:13
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 <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	26 NOV 2020 08:34:06
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 03 DEC 2020 08:02:42

Patient Cloud Open Date & Time 03 DEC 2020 00:01

Patient Cloud Close Date & Time 07 DEC 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 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	10 DEC 2020 10:47:28
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 17 DEC 2020 09:01:05

Patient Cloud Open Date & Time 17 DEC 2020 00:01

Patient Cloud Close Date & Time 21 DEC 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 09:01:47
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	31 DEC 2020 19:20:30
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 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	08 JAN 2021 17:02:17
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 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	16 JAN 2021 12:00:44
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 <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	23 JAN 2021 12:49:42
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 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 JAN 2021 12:01:22
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 16:06:20
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 09:00:31
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 FEB 2021 21:52:24
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 25 FEB 2021 18:00:32

Patient Cloud Open Date & Time 25 FEB 2021 00:01

Patient Cloud Close Date & Time 01 MAR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 06:44:33
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 MAR 2021 05:57:39
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 18 MAR 2021 09:32:57

Patient Cloud Open Date & Time 18 MAR 2021 00:01

Patient Cloud Close Date & Time 22 MAR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 21:36:25
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 01 APR 2021 07:21:26

Patient Cloud Open Date & Time 01 APR 2021 00:01

Patient Cloud Close Date & Time 05 APR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 APR 2021 07:28:31
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 229

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 236

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 243

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	20 MAY 2021 00:01
Patient Cloud Close Date & Time	24 MAY 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 320

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 30 AUG 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 460

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 13 DEC 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 31 JAN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 600

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 10 OCT 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 17 OCT 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 24 OCT 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2022 00:01
Patient Cloud Close Date & Time	07 NOV 2022 23:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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°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

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3712013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:20:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:16:01

US3712013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:27:10

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:27:10

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:52:10

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 01:08:38

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 APR 2021

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

Folder OID VISIT4

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 01:08:38

Generated On: 10 Jun 2021 09:20:39

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 01:08:38

Generated On: 10 Jun 2021 09:20:39

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.

US3712013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 01:08:38

Generated On: 10 Jun 2021 09:20:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 06 APR 2021

Collection time (*00:00-23:59*) 09:19 (24 HR)

Collection date and time (derived) 06 APR 2021 09:19

US3712013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:08:38

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) _____

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

Comments _____

If Contact Not Made, please provide Comments _____

US3712013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3712013

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:20:39

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"/>

US3712013

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:20:39

Generate Next COVID-19 Assessment

Yes

No

US3712013

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

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 JAN 2021

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

Folder OID UNBLND_DECIDE

US3712013

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3712013

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3712013

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 09:28
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3712013

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	26 JAN 2021
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 10:34
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3712013

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

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

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.

US3712013

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

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

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

What was the treatment time? (00:00-23:59) 10:04 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 10:04

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

US3712013

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 JAN 2021

Collection time (*00:00-23:59*) 09:20 (24 HR)

Collection date and time (derived) 26 JAN 2021 09:20

US3712013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 26 JAN 2021

Collection time (*00:00 - 23:59*) 09:22

Collection Date and Time (derived) 26 JAN 2021 09:22

US3712013

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

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:52:10

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:10

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3712013

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 FEB 2021

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

Folder OID OLD29

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

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 (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:04 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:04
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	57 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

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 (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:36 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:36
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3712013

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

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.

US3712013

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 10:05

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

US3712013

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:52:10

Generated On: 10 Jun 2021 09:20:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3712013

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:52:10

Generated On: 10 Jun 2021 09:20:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3712013

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 26 MAR 2021

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

Folder OID OLD57

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

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

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712013

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

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.

US3712013

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 26 MAR 2021

Collection time (*00:00-23:59*) 09:17 (24 HR)

Collection date and time (derived) 26 MAR 2021 09:17

US3712013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:17:37

Generated On: 10 Jun 2021 09:20:39

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 22:14:57

Generated On: 10 Jun 2021 09:20:39

AEID USA-US068-2021-MRNA-1273-P30
1000017

Adverse event PNEUMONIA

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 05 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 21 SEP 2020

Hospital Discharge Date (dd MMM yyyy) 22 SEP 2020

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 22:14:57

Generated On: 10 Jun 2021 09:20:39

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 22:14:57

Generated On: 10 Jun 2021 09:20:39

SUBJECT NOTIFIED STAFF DURING HIS DAY 15 PHONE CALL ON 22 SEPTEMBER 2020 THAT HE WAS IN THE HOSPITAL. ON 18 SEPTEMBER 2020 SUBJECT STATED HAVING PAIN IN THEIR LEFT SIDE, CHEST AND BACK. ON 21 SEPTEMBER 2020 SUBJECT WAS ADVISED BY PCP TO GO TO THE HOSPITAL. UPON ARRIVAL TO ED SUBJECT HAS EKG, CHEST X-RAY, AND CT SCAN DONE. CT SCAN SHOWED PNEUMONIA IN LEFT LUNG. COVID-19 TEST WAS OBTAINED AND RESULTED NEGATIVE. SUBJECT PRESCRIBED DOXYCYCLINE 100MG TAB BID X 4 DAYS AND CEFDINIR 300MG TAB BID X 4 DAYS. CT THORAX: MEDICAL LEFT LOWER LOVE OPACITY IS AT LEAST PARTIALLY ATELECTATIC ALTHOUGH CANNOT EXCLUDE DEVELOPING PNEUMONIA. TRACE LEFT PLEURAL EFFUSION. RIGHT DIAPHRAGMATIC EVENTRATION AND ADJACENT ATELECTASIS. EKG: NORMAL CHEST X-RAY: ELEVATED RIGHT HEMIDIAPHRAGM NO CONGESTION AND NO PNEUMOTHORAX.

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

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

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

Yes

No

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

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication FLONASE

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input checked="" type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication FAMOTIDINE

Prophylaxis Yes
No

Indication ACID REFLUX

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication FISH OIL

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication FOLIC ACID (TABLET)

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication NIACIN

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication PANTOPRAZOLE

Prophylaxis Yes
No

Indication ACID REFLUX

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication VITAMIN B12

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ALLEGRA

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 180

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication BENADRYL

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 80

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication TUMS (CALCIUM CARBONATE)

Prophylaxis Yes
No

Indication ACID REFLUX

Dose per administration 2000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 1990

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication DOXYCYCLINE

Prophylaxis Yes
No

Indication PNEUMONIA

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
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

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*) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 25 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication CEFDINIR

Prophylaxis Yes
No

Indication PNEUMONIA

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

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*) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 25 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes
No

Indication PNEUMONIA

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication GENERALIZED NON-CARDIAC CHEST PAIN

Dose per administration 325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication CEFTRIAXONE

Prophylaxis Yes
No

Indication PNEUMONIA

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 22 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication CETIRIZINE HYDROCHLORIDE

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)

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US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 15 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA PREVENTIVE

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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*) 22 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 22 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ATORVASTATIN

Prophylaxis Yes
No

Indication HYPERLIPIDEMIA

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 15 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 15 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication MELATONIN

Prophylaxis Yes
No

Indication INSOMNIA

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

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*) 31 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT
TREATMENT

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 _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication LOVENOX

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT
TREATMENT

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

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) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication MELATONIN

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT TREATMENT

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ONDANSETRON

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT
TREATMENT

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication FAMOTIDINE

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT
TREATMENT

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

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

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) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication ONDANSETRON

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT
TREATMENT

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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) 21 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication FEXOFENADINE

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT TREATMENT

Dose per administration 180

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	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)	21 SEP 2020
--------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020
--	-------------

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"/>

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication REVATIO

Prophylaxis Yes
No

Indication PNEUMONIA INPATIENT
TREATMENT

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

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

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)	21 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020
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"/>

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

Name of Medication TETANUS DIPHTHERIA
VACCINE

Prophylaxis Yes
No

Indication TETANUS PROPHYLAXIS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 18 Apr 2021 23:27:25

Generated On: 10 Jun 2021 09:20:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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
No

If not Ongoing, End date (dd MMM yyyy) 11 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3712013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3712013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:20:39

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

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

SAEID	USA-US068-2021-MRNA-1273-P30 1000017
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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

SAEID	USA-US068-2021-MRNA-1273-P301000017
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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/MAR/2021 12:20
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.	<input checked="" type="checkbox"/> True

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Apr 2021 23:52:09

Generated On: 10 Jun 2021 09:20:39

SAEID	USA-US068-2021-MRNA-1273-P301000017
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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/MAR/2021 06:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

Audit

US3712013 (Prod: Alliance for Multispecialty Research, LLC)

US3712013

Form: Participant Creation

Generated On: 10 Jun 2021 09:20:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'US3712013'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:44:39

US3712013

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:04

US3712013

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:44:40

US3712013

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:04

US3712013

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'SCRN'	System	28 Aug 2020 13:30:04

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:44:41

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '71'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'YEARS'	System	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '71'	System	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '1'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:20:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:39

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Aug 2020'	System	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '2020'	System	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:31:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 19:09:27
Query 'Data is required. Please complete.' answered with 'Pending randomization' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 14:34:19
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 13:30:52
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 13:30:52

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:44:40

US3712013

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:20:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '1'	System	08 Sep 2020 16:31:32

US3712013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:31:32

US3712013

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:20:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:23

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:49
Data point term sent to Coder	System	08 Sep 2020 20:20:52
User entered 'seasonal allergies'	(b) (4), (b) (6)	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'un UNK 1979'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Jan 1979'	System	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '1979'	System	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:20:51

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
Data point term sent to Coder	System	08 Sep 2020 20:21:53
User entered 'myopia'	(b) (4), (b) (6)	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'un UNK 1958'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Jan 1958'	System	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '1958'	System	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:21:06

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
Data point term sent to Coder	System	08 Sep 2020 20:21:57
User entered 'Acid reflux'	(b) (4), (b) (6)	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'UN UNK 1990' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:46:16
User entered 'un UNK 2015'	(b) (4), (b) (6)	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Jan 1990'	System	08 Oct 2020 12:46:16
User entered 'Jan 2015'	System	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '1990'	System	08 Oct 2020 12:46:16
User entered '2015'	System	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:21:31

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
Data point term sent to Coder	System	08 Sep 2020 20:21:57
User entered 'Insomnia'	(b) (4), (b) (6)	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Jan 2019'	System	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '2019'	System	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	08 Sep 2020 20:21:54

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 14:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 14:58:45
Data point term sent to Coder	System	03 Feb 2021 14:57:57
User entered 'premature ventricular complexes'	(b) (4), (b) (6)	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Jan 2013'	System	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '2013'	System	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	03 Feb 2021 14:57:36

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 14:59:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 14:59:45
Data point term sent to Coder	System	03 Feb 2021 14:58:59
User entered 'hyperlipidemia'	(b) (4), (b) (6)	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'Jan 1995'	System	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '1995'	System	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered empty.	System	03 Feb 2021 14:58:11

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '13:10'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '27 Aug 2020 13:10'	System	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '162.8' cm	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19
DataPoint set to visible.	System	08 Sep 2020 16:31:32

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '90.9' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19
DataPoint set to visible.	System	08 Sep 2020 16:31:32

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered '34.29692'	System	08 Sep 2020 20:13:19
DataPoint set to visible.	System	08 Sep 2020 16:31:32

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'kg/m2'	System	08 Sep 2020 20:13:19
DataPoint set to visible.	System	08 Sep 2020 16:31:32

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '65'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'bpm'	System	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'breaths/min'	System	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '117'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'mmHg'	System	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '80'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User entered 'mmHg'	System	08 Sep 2020 20:13:19

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25

US3712013

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25

US3712013

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:14:01

US3712013

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:47:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 20:43:05
User entered '27 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 20:14:01

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'restaurants, and grocery stores'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:20:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:19:25
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:03

US3712013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:43:05

US3712013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:43:05

US3712013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:43:05

US3712013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'VISIT1'	System	08 Sep 2020 20:43:05

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:35:15

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '190215'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:35:15

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:35:15

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

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 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:04

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

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 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:04

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:04

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:04

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:04

US3712013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:20:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:34:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:16:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:16:02

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '162.8' cm	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '90.7' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '162.8' cm	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '90.7' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '10:17'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '08 Sep 2020 10:17'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '59'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'bpm'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'breaths/min'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '122'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '85'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '162.8' cm	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '90.7' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '12:43'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '08 Sep 2020 12:43'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '61'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'bpm'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'breaths/min'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '129'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '86'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	08 Sep 2020 20:47:08

US3712013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:14

US3712013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:14

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

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 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '12:08'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '08 Sep 2020 12:08'	System	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'ONCE'	System	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 16:32:42

US3712013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:49

US3712013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:49

US3712013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '10:33'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:47:49

US3712013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '08 Sep 2020 10:33'	System	08 Sep 2020 20:47:49

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '11:36'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '08 Sep 2020 11:36'	System	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:52:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:52:30
User entered '11:36'	(b) (4), (b) (6)	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	12 Feb 2021 19:52:30
User entered '08 Sep 2020 11:36'	System	08 Sep 2020 20:48:02

US3712013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:32:12

US3712013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	08 Sep 2020 16:32:12

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:22', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ba07514-0ba0-481e-8bae-35db125d1d17'	System	08 Sep 2020 16:42:39
User entered 'Yes (Y)'	System	08 Sep 2020 16:42:39

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ba07514-0ba0-481e-8bae-35db125d1d17'	System	08 Sep 2020 16:42:39
User entered '98.4'	System	08 Sep 2020 16:42:39

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:31', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ba07514-0ba0-481e-8bae-35db125d1d17'	System	08 Sep 2020 16:42:39
User entered 'No (N)'	System	08 Sep 2020 16:42:39

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ba07514-0ba0-481e-8bae-35db125d1d17'	System	08 Sep 2020 16:42:39
User entered '08 Sep 2020 12:42'	System	08 Sep 2020 16:42:39

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 12:28'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 14:58'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0c6b220f-76e6-459f-bd62-98d2d9bf7c91'	System	08 Sep 2020 21:34:29
User entered 'Yes (Y)'	System	08 Sep 2020 21:34:29

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:19', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0c6b220f-76e6-459f-bd62-98d2d9bf7c91' User entered '97.6'	System	08 Sep 2020 21:34:29
	System	08 Sep 2020 21:34:29

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:22', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0c6b220f-76e6-459f-bd62-98d2d9bf7c91'	System	08 Sep 2020 21:34:29
User entered 'No (N)'	System	08 Sep 2020 21:34:29

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0c6b220f-76e6-459f-bd62-98d2d9bf7c91' User entered '08 Sep 2020 17:34'	System	08 Sep 2020 21:34:29
	System	08 Sep 2020 21:34:29

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 15:53'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 2'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf2a5942-ed29-4dbf-adb2-253ed00d42b7'	System	09 Sep 2020 22:56:45
User entered 'Yes (Y)'	System	09 Sep 2020 22:56:45

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf2a5942-ed29-4dbf-adb2-253ed00d42b7' User entered '97.5'	System	09 Sep 2020 22:56:45
	System	09 Sep 2020 22:56:45

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf2a5942-ed29-4dbf-adb2-253ed00d42b7'	System	09 Sep 2020 22:56:45
User entered 'No (N)'	System	09 Sep 2020 22:56:45

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:43', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf2a5942-ed29-4dbf-adb2-253ed00d42b7'	System	09 Sep 2020 22:56:45
User entered '09 Sep 2020 18:56'	System	09 Sep 2020 22:56:45

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 3'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:57:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf7b78e0-671b-4841-ac82-adafd28c2024' User entered 'Yes (Y)'	System	10 Sep 2020 23:58:34
	System	10 Sep 2020 23:58:34

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:23', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf7b78e0-671b-4841-ac82-adafd28c2024' User entered '96.8'	System	10 Sep 2020 23:58:34
	System	10 Sep 2020 23:58:34

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:25', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf7b78e0-671b-4841-ac82-adafd28c2024'	System	10 Sep 2020 23:58:34
User entered 'No (N)'	System	10 Sep 2020 23:58:34

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:29', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'bf7b78e0-671b-4841-ac82-adafd28c2024'	System	10 Sep 2020 23:58:34
User entered '10 Sep 2020 19:58'	System	10 Sep 2020 23:58:34

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 4'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:01:37', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '666baf25-a49b-43d4-a0b3-29831ce87f1c' User entered 'Yes (Y)'	System	11 Sep 2020 23:02:18
	System	11 Sep 2020 23:02:18

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:01:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '666baf25-a49b-43d4-a0b3-29831ce87f1c' User entered '97.8'	System	11 Sep 2020 23:02:18
	System	11 Sep 2020 23:02:18

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:01:45', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '666baf25-a49b-43d4-a0b3-29831ce87f1c' User entered 'No (N)'	System	11 Sep 2020 23:02:18
	System	11 Sep 2020 23:02:18

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:01:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '666baf25-a49b-43d4-a0b3-29831ce87f1c' User entered '11 Sep 2020 19:01'	System	11 Sep 2020 23:02:18
	System	11 Sep 2020 23:02:18

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 5'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:01:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eed31ae-4fff-4f1d-a9d6-fc115dd98aa7'	System	12 Sep 2020 23:02:08
User entered 'Yes (Y)'	System	12 Sep 2020 23:02:08

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:01:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eed31ae-4fff-4f1d-a9d6-fc115dd98aa7' User entered '97.4'	System	12 Sep 2020 23:02:08
	System	12 Sep 2020 23:02:08

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eed31ae-4fff-4f1d-a9d6-fc115dd98aa7'	System	12 Sep 2020 23:02:08
User entered 'No (N)'	System	12 Sep 2020 23:02:08

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:05', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eed31ae-4fff-4f1d-a9d6-fc115dd98aa7'	System	12 Sep 2020 23:02:08
User entered '12 Sep 2020 19:02'	System	12 Sep 2020 23:02:08

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 6'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:02', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '147a5b18-9784-495d-8b3c-4724f94e2b2f' User entered 'Yes (Y)'	System	13 Sep 2020 23:02:16
	System	13 Sep 2020 23:02:16

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '147a5b18-9784-495d-8b3c-4724f94e2b2f' User entered '97.5'	System	13 Sep 2020 23:02:16
	System	13 Sep 2020 23:02:16

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '147a5b18-9784-495d-8b3c-4724f94e2b2f' User entered 'No (N)'	System	13 Sep 2020 23:02:16
	System	13 Sep 2020 23:02:16

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:15', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '147a5b18-9784-495d-8b3c-4724f94e2b2f' User entered '13 Sep 2020 19:02'	System	13 Sep 2020 23:02:16
	System	13 Sep 2020 23:02:16

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 7'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:28', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b58bf996-4457-42ef-8314-c62ea0d15203'	System	14 Sep 2020 22:25:42
User entered 'Yes (Y)'	System	14 Sep 2020 22:25:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:32', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b58bf996-4457-42ef-8314-c62ea0d15203' User entered '97.7'	System	14 Sep 2020 22:25:42
	System	14 Sep 2020 22:25:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:35', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b58bf996-4457-42ef-8314-c62ea0d15203'	System	14 Sep 2020 22:25:42
User entered 'No (N)'	System	14 Sep 2020 22:25:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b58bf996-4457-42ef-8314-c62ea0d15203'	System	14 Sep 2020 22:25:42
User entered '14 Sep 2020 18:25'	System	14 Sep 2020 22:25:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac2256e1-fe46-4b8a-82a5-a1bd24b1bb0d'	System	08 Sep 2020 16:43:03
User entered 'None (1)'	System	08 Sep 2020 16:43:03

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:45', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac2256e1-fe46-4b8a-82a5-a1bd24b1bb0d'	System	08 Sep 2020 16:43:03
User entered 'No (N)'	System	08 Sep 2020 16:43:03

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:47', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac2256e1-fe46-4b8a-82a5-a1bd24b1bb0d'	System	08 Sep 2020 16:43:03
User entered 'No (N)'	System	08 Sep 2020 16:43:03

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:42:53', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac2256e1-fe46-4b8a-82a5-a1bd24b1bb0d'	System	08 Sep 2020 16:43:03
User entered 'None (1)'	System	08 Sep 2020 16:43:03

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac2256e1-fe46-4b8a-82a5-a1bd24b1bb0d' User entered '08 Sep 2020 12:43'	System	08 Sep 2020 16:43:03
	System	08 Sep 2020 16:43:03

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 12:28'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 14:58'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:31', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f9a5aaf6-bced-4af8-bdb0-a164ff1c461d'	System	08 Sep 2020 21:34:56
User entered 'None (1)'	System	08 Sep 2020 21:34:56

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f9a5aaf6-bced-4af8-bdb0-a164ff1c461d'	System	08 Sep 2020 21:34:56
User entered 'No (N)'	System	08 Sep 2020 21:34:56

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:43', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f9a5aaf6-bced-4af8-bdb0-a164ff1c461d'	System	08 Sep 2020 21:34:56
User entered 'No (N)'	System	08 Sep 2020 21:34:56

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:49', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f9a5aaf6-bced-4af8-bdb0-a164ff1c461d'	System	08 Sep 2020 21:34:56
User entered 'None (1)'	System	08 Sep 2020 21:34:56

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f9a5aaf6-bced-4af8-bdb0-a164ff1c461d' User entered '08 Sep 2020 17:34'	System	08 Sep 2020 21:34:56
	System	08 Sep 2020 21:34:56

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 15:53'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 2'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:47', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac828456-f888-406c-b742-d17fb15609e4'	System	09 Sep 2020 22:57:02
User entered 'None (1)'	System	09 Sep 2020 22:57:02

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:50', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac828456-f888-406c-b742-d17fb15609e4'	System	09 Sep 2020 22:57:02
User entered 'No (N)'	System	09 Sep 2020 22:57:02

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac828456-f888-406c-b742-d17fb15609e4'	System	09 Sep 2020 22:57:02
User entered 'No (N)'	System	09 Sep 2020 22:57:02

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:56:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac828456-f888-406c-b742-d17fb15609e4'	System	09 Sep 2020 22:57:02
User entered 'None (1)'	System	09 Sep 2020 22:57:02

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ac828456-f888-406c-b742-d17fb15609e4' User entered '09 Sep 2020 18:57'	System	09 Sep 2020 22:57:02
	System	09 Sep 2020 22:57:02

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 3'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '458b2e9b-ab2f-4edc-9d74-433a0bb42dae' User entered 'None (1)'	System	10 Sep 2020 23:58:46
	System	10 Sep 2020 23:58:46

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '458b2e9b-ab2f-4edc-9d74-433a0bb42dae' User entered 'No (N)'	System	10 Sep 2020 23:58:46
	System	10 Sep 2020 23:58:46

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '458b2e9b-ab2f-4edc-9d74-433a0bb42dae' User entered 'No (N)'	System	10 Sep 2020 23:58:46
	System	10 Sep 2020 23:58:46

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:41', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '458b2e9b-ab2f-4edc-9d74-433a0bb42dae' User entered 'None (1)'	System	10 Sep 2020 23:58:46
	System	10 Sep 2020 23:58:46

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:44', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '458b2e9b-ab2f-4edc-9d74-433a0bb42dae' User entered '10 Sep 2020 19:58'	System	10 Sep 2020 23:58:46
	System	10 Sep 2020 23:58:46

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 4'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:01:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7622a52a-15ab-4c9c-9193-8208e5f8663c' User entered 'None (1)'	System	11 Sep 2020 23:03:13
	System	11 Sep 2020 23:03:13

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:01:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7622a52a-15ab-4c9c-9193-8208e5f8663c' User entered 'No (N)'	System	11 Sep 2020 23:03:13
	System	11 Sep 2020 23:03:13

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7622a52a-15ab-4c9c-9193-8208e5f8663c' User entered 'No (N)'	System	11 Sep 2020 23:03:13
	System	11 Sep 2020 23:03:13

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:03', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7622a52a-15ab-4c9c-9193-8208e5f8663c' User entered 'None (1)'	System	11 Sep 2020 23:03:13
	System	11 Sep 2020 23:03:13

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7622a52a-15ab-4c9c-9193-8208e5f8663c' User entered '11 Sep 2020 19:02'	System	11 Sep 2020 23:03:13
	System	11 Sep 2020 23:03:13

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 5'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:11', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'd463cb1d-98de-47fe-8f1c-e726d13b7353'	System	12 Sep 2020 23:02:31
User entered 'None (1)'	System	12 Sep 2020 23:02:31

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'd463cb1d-98de-47fe-8f1c-e726d13b7353'	System	12 Sep 2020 23:02:31
User entered 'No (N)'	System	12 Sep 2020 23:02:31

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'd463cb1d-98de-47fe-8f1c-e726d13b7353'	System	12 Sep 2020 23:02:31
User entered 'No (N)'	System	12 Sep 2020 23:02:31

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:20', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'd463cb1d-98de-47fe-8f1c-e726d13b7353'	System	12 Sep 2020 23:02:31
User entered 'None (1)'	System	12 Sep 2020 23:02:31

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:26', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'd463cb1d-98de-47fe-8f1c-e726d13b7353'	System	12 Sep 2020 23:02:31
User entered '12 Sep 2020 19:02'	System	12 Sep 2020 23:02:31

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 6'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:19', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b5d3a778-d829-4bfb-8471-887df00c76e1' User entered 'None (1)'	System	13 Sep 2020 23:02:35
	System	13 Sep 2020 23:02:35

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:21', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b5d3a778-d829-4bfb-8471-887df00c76e1' User entered 'No (N)'	System	13 Sep 2020 23:02:35
	System	13 Sep 2020 23:02:35

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:23', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b5d3a778-d829-4bfb-8471-887df00c76e1' User entered 'No (N)'	System	13 Sep 2020 23:02:35
	System	13 Sep 2020 23:02:35

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b5d3a778-d829-4bfb-8471-887df00c76e1' User entered 'None (1)'	System	13 Sep 2020 23:02:35
	System	13 Sep 2020 23:02:35

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:30', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b5d3a778-d829-4bfb-8471-887df00c76e1' User entered '13 Sep 2020 19:02'	System	13 Sep 2020 23:02:35
	System	13 Sep 2020 23:02:35

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 7'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:43', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cdbac6c8-6a64-4657-a3a2-7e099cd9319f'	System	14 Sep 2020 22:25:57
User entered 'None (1)'	System	14 Sep 2020 22:25:57

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:46', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cdbac6c8-6a64-4657-a3a2-7e099cd9319f' User entered 'No (N)'	System	14 Sep 2020 22:25:57
	System	14 Sep 2020 22:25:57

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:48', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cdbac6c8-6a64-4657-a3a2-7e099cd9319f' User entered 'No (N)'	System	14 Sep 2020 22:25:57
	System	14 Sep 2020 22:25:57

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:50', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cdbac6c8-6a64-4657-a3a2-7e099cd9319f' User entered 'None (1)'	System	14 Sep 2020 22:25:57
	System	14 Sep 2020 22:25:57

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cdbac6c8-6a64-4657-a3a2-7e099cd9319f' User entered '14 Sep 2020 18:25'	System	14 Sep 2020 22:25:57
	System	14 Sep 2020 22:25:57

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'None (0)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'None (0)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'None (0)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:15', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'None (0)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:18', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'None (0)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:20', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'None (0)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:23', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered 'No (N)'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T12:43:32', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6c69552b-2798-4cc8-96dc-a76055fded25' User entered '08 Sep 2020 12:43'	System	08 Sep 2020 16:43:39
	System	08 Sep 2020 16:43:39

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 12:28'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 14:58'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:34:59', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'None (0)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'None (0)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:03', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'None (0)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:05', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'None (0)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'None (0)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'None (0)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered 'No (N)'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-08T17:35:18', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6859c733-87ad-4b75-a924-580e7d74d512'	System	08 Sep 2020 21:35:21
User entered '08 Sep 2020 17:35'	System	08 Sep 2020 21:35:21

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Sep 2020 15:53'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 2'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:04', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9'	System	09 Sep 2020 22:57:27
User entered 'None (0)'	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:06', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9' User entered 'None (0)'	System	09 Sep 2020 22:57:27
	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9'	System	09 Sep 2020 22:57:27
User entered 'None (0)'	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9' User entered 'None (0)'	System	09 Sep 2020 22:57:27
	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9' User entered 'None (0)'	System	09 Sep 2020 22:57:27
	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:14', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9' User entered 'None (0)'	System	09 Sep 2020 22:57:27
	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9' User entered 'No (N)'	System	09 Sep 2020 22:57:27
	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-09T18:57:24', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '72f8a5b4-e8ac-488e-9903-835bef6390c9' User entered '09 Sep 2020 18:57'	System	09 Sep 2020 22:57:27
	System	09 Sep 2020 22:57:27

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 3'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:48', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'None (0)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:50', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'None (0)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'None (0)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:54', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'None (0)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:56', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'None (0)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:58:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'None (0)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:59:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered 'No (N)'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-10T19:59:05', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c040d054-7441-4799-b10e-25366f6bcfe1' User entered '10 Sep 2020 19:59'	System	11 Sep 2020 23:01:59
	System	11 Sep 2020 23:01:59

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 4'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2' User entered 'None (0)'	System	11 Sep 2020 23:03:23
	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:44', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2' User entered 'None (0)'	System	11 Sep 2020 23:03:23
	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:46', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2'	System	11 Sep 2020 23:03:23
User entered 'None (0)'	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:47', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2' User entered 'None (0)'	System	11 Sep 2020 23:03:23
	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:50', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2' User entered 'None (0)'	System	11 Sep 2020 23:03:23
	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2'	System	11 Sep 2020 23:03:23
User entered 'None (0)'	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:02:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2' User entered 'No (N)'	System	11 Sep 2020 23:03:23
	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-11T19:03:03', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '76507054-0670-47d4-aa0e-c23421e99ca2'	System	11 Sep 2020 23:03:23
User entered '11 Sep 2020 19:03'	System	11 Sep 2020 23:03:23

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 5'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671'	System	12 Sep 2020 23:03:02
User entered 'No interference with activity (1)'	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671' User entered 'None (0)'	System	12 Sep 2020 23:03:02
	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671' User entered 'None (0)'	System	12 Sep 2020 23:03:02
	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671' User entered 'None (0)'	System	12 Sep 2020 23:03:02
	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:47', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671'	System	12 Sep 2020 23:03:02
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671' User entered 'None (0)'	System	12 Sep 2020 23:03:02
	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671' User entered 'No (N)'	System	12 Sep 2020 23:03:02
	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-12T19:02:59', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4a02979f-4d6e-4436-bdab-8de1d7ed2671'	System	12 Sep 2020 23:03:02
User entered '12 Sep 2020 19:02'	System	12 Sep 2020 23:03:02

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 6'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:34', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'None (0)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:37', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'None (0)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:39', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'None (0)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:41', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'None (0)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:44', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'None (0)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:46', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'None (0)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:49', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered 'No (N)'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-13T19:02:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4e2f88c4-032c-486a-8e43-21c53b25b07b' User entered '13 Sep 2020 19:02'	System	14 Sep 2020 22:25:31
	System	14 Sep 2020 22:25:31

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 7'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:25:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'None (0)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:11', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'None (0)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:18', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'None (0)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:23', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'None (0)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:25', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'None (0)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'None (0)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:30', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered 'No (N)'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-09-14T18:26:37', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a0efe94e-398f-43f9-9df7-49a5de985ffc'	System	14 Sep 2020 22:26:38
User entered '14 Sep 2020 18:26'	System	14 Sep 2020 22:26:38

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:32:42

US3712013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:49:46

US3712013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:49:46

US3712013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:49:46

US3712013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:49:46

US3712013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:50:23

US3712013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	30 Sep 2020 14:50:23

US3712013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:50:56

US3712013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:50:56

US3712013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:50:56

US3712013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:50:56

US3712013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:51:55

US3712013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	30 Sep 2020 14:51:55

US3712013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:52:16

US3712013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:52:16

US3712013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:52:16

US3712013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:52:16

US3712013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:04

US3712013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	30 Sep 2020 14:54:04

US3712013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:53

US3712013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:53

US3712013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:57:53

US3712013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'VISIT2'	System	05 Oct 2020 15:57:53

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '09:05'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '05 Oct 2020 09:05'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '67'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'bpm'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'breaths/min'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '118'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '11:05'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '05 Oct 2020 11:05'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'bpm'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'breaths/min'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '120'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '87'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'mmHg'	System	05 Oct 2020 15:59:07

US3712013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:11

US3712013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:59:11

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

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 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '10:33'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '05 Oct 2020 10:33'	System	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'ONCE'	System	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 14:41:25

US3712013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:00:16

US3712013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:00:16

US3712013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '09:51'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:00:16

US3712013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '05 Oct 2020 09:51'	System	05 Oct 2020 16:00:16

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:20:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '09:57'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '05 Oct 2020 09:57'	System	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:52:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:52:38
User entered '09:57'	(b) (4), (b) (6)	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	12 Feb 2021 19:52:38
User entered '05 Oct 2020 09:57'	System	05 Oct 2020 16:00:28

US3712013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:41:50

US3712013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	05 Oct 2020 14:41:50

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:02', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8d59e28e-70bb-4dd4-a9dc-2036141fa473' User entered 'Yes (Y)'	System	05 Oct 2020 15:14:30
	System	05 Oct 2020 15:14:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8d59e28e-70bb-4dd4-a9dc-2036141fa473' User entered '97.9'	System	05 Oct 2020 15:14:30
	System	05 Oct 2020 15:14:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8d59e28e-70bb-4dd4-a9dc-2036141fa473'	System	05 Oct 2020 15:14:30
User entered 'No (N)'	System	05 Oct 2020 15:14:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:20', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8d59e28e-70bb-4dd4-a9dc-2036141fa473' User entered '05 Oct 2020 11:14'	System	05 Oct 2020 15:14:30
	System	05 Oct 2020 15:14:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 10:53'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 13:23'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:03:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f4b43998-023f-4744-b2d6-3e4fcdd43c5f'	System	06 Oct 2020 02:04:10
User entered 'Yes (Y)'	System	06 Oct 2020 02:04:10

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:03:56', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f4b43998-023f-4744-b2d6-3e4fcdd43c5f' User entered '97.5'	System	06 Oct 2020 02:04:10
	System	06 Oct 2020 02:04:10

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f4b43998-023f-4744-b2d6-3e4fcdd43c5f'	System	06 Oct 2020 02:04:10
User entered 'No (N)'	System	06 Oct 2020 02:04:10

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:06', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f4b43998-023f-4744-b2d6-3e4fcdd43c5f' User entered '05 Oct 2020 22:04'	System	06 Oct 2020 02:04:10
	System	06 Oct 2020 02:04:10

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 14:18'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 2'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:01:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '333ad254-a28e-4d02-91dd-db26334a49ff' User entered 'Yes (Y)'	System	06 Oct 2020 21:02:08
	System	06 Oct 2020 21:02:08

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:01:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '333ad254-a28e-4d02-91dd-db26334a49ff' User entered '97.9'	System	06 Oct 2020 21:02:08
	System	06 Oct 2020 21:02:08

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '333ad254-a28e-4d02-91dd-db26334a49ff' User entered 'No (N)'	System	06 Oct 2020 21:02:08
	System	06 Oct 2020 21:02:08

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:06', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '333ad254-a28e-4d02-91dd-db26334a49ff' User entered '06 Oct 2020 17:02'	System	06 Oct 2020 21:02:08
	System	06 Oct 2020 21:02:08

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 3'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:25', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '02ebc955-af1e-4282-8ab8-7f8476169c3a' User entered 'Yes (Y)'	System	07 Oct 2020 21:04:37
	System	07 Oct 2020 21:04:37

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:29', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '02ebc955-af1e-4282-8ab8-7f8476169c3a' User entered '98.0'	System	07 Oct 2020 21:04:37
	System	07 Oct 2020 21:04:37

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:31', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '02ebc955-af1e-4282-8ab8-7f8476169c3a'	System	07 Oct 2020 21:04:37
User entered 'No (N)'	System	07 Oct 2020 21:04:37

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:34', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '02ebc955-af1e-4282-8ab8-7f8476169c3a' User entered '07 Oct 2020 17:04'	System	07 Oct 2020 21:04:37
	System	07 Oct 2020 21:04:37

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 4'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '94b658d3-55fa-4f45-8402-6db07d2bb519' User entered 'Yes (Y)'	System	08 Oct 2020 21:03:22
	System	08 Oct 2020 21:03:22

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '94b658d3-55fa-4f45-8402-6db07d2bb519' User entered '97.5'	System	08 Oct 2020 21:03:22
	System	08 Oct 2020 21:03:22

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:14', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '94b658d3-55fa-4f45-8402-6db07d2bb519'	System	08 Oct 2020 21:03:22
User entered 'No (N)'	System	08 Oct 2020 21:03:22

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '94b658d3-55fa-4f45-8402-6db07d2bb519' User entered '08 Oct 2020 17:03'	System	08 Oct 2020 21:03:22
	System	08 Oct 2020 21:03:22

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 5'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:02', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a6760e55-9359-4e55-b373-c2fe1e702d66' User entered 'Yes (Y)'	System	09 Oct 2020 19:34:31
	System	09 Oct 2020 19:34:31

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:23', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a6760e55-9359-4e55-b373-c2fe1e702d66' User entered '98.0'	System	09 Oct 2020 19:34:31
	System	09 Oct 2020 19:34:31

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:26', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a6760e55-9359-4e55-b373-c2fe1e702d66'	System	09 Oct 2020 19:34:31
User entered 'No (N)'	System	09 Oct 2020 19:34:31

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:28', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a6760e55-9359-4e55-b373-c2fe1e702d66' User entered '09 Oct 2020 15:34'	System	09 Oct 2020 19:34:31
	System	09 Oct 2020 19:34:31

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 6'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:09', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6a53535a-e4ed-4451-b6e0-cf7c715f52e9' User entered 'Yes (Y)'	System	10 Oct 2020 21:03:30
	System	10 Oct 2020 21:03:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:21', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6a53535a-e4ed-4451-b6e0-cf7c715f52e9' User entered '97.6'	System	10 Oct 2020 21:03:30
	System	10 Oct 2020 21:03:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:24', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6a53535a-e4ed-4451-b6e0-cf7c715f52e9' User entered 'No (N)'	System	10 Oct 2020 21:03:30
	System	10 Oct 2020 21:03:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6a53535a-e4ed-4451-b6e0-cf7c715f52e9' User entered '10 Oct 2020 17:03'	System	10 Oct 2020 21:03:30
	System	10 Oct 2020 21:03:30

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 7'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:23:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a8b55e7d-ed42-4c85-840e-0ac5c0d995ac' User entered 'Yes (Y)'	System	11 Oct 2020 21:23:59
	System	11 Oct 2020 21:23:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:23:49', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a8b55e7d-ed42-4c85-840e-0ac5c0d995ac' User entered '96.3'	System	11 Oct 2020 21:23:59
	System	11 Oct 2020 21:23:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:23:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a8b55e7d-ed42-4c85-840e-0ac5c0d995ac' User entered 'No (N)'	System	11 Oct 2020 21:23:59
	System	11 Oct 2020 21:23:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:23:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a8b55e7d-ed42-4c85-840e-0ac5c0d995ac' User entered '11 Oct 2020 17:23'	System	11 Oct 2020 21:23:59
	System	11 Oct 2020 21:23:59

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'fd364609-14ec-4c9e-b999-80cd20ad7404'	System	05 Oct 2020 15:14:46
User entered 'None (1)'	System	05 Oct 2020 15:14:46

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:30', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'fd364609-14ec-4c9e-b999-80cd20ad7404'	System	05 Oct 2020 15:14:46
User entered 'No (N)'	System	05 Oct 2020 15:14:46

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:34', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'fd364609-14ec-4c9e-b999-80cd20ad7404' User entered 'No (N)'	System	05 Oct 2020 15:14:46
	System	05 Oct 2020 15:14:46

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:37', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'fd364609-14ec-4c9e-b999-80cd20ad7404'	System	05 Oct 2020 15:14:46
User entered 'None (1)'	System	05 Oct 2020 15:14:46

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:45', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'fd364609-14ec-4c9e-b999-80cd20ad7404' User entered '05 Oct 2020 11:14'	System	05 Oct 2020 15:14:46
	System	05 Oct 2020 15:14:46

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 10:53'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 13:23'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c4fbd0c2-331a-4115-a915-470dc28f1793'	System	06 Oct 2020 02:04:24
User entered 'None (1)'	System	06 Oct 2020 02:04:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c4fbd0c2-331a-4115-a915-470dc28f1793' User entered 'No (N)'	System	06 Oct 2020 02:04:24
	System	06 Oct 2020 02:04:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:15', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c4fbd0c2-331a-4115-a915-470dc28f1793'	System	06 Oct 2020 02:04:24
User entered 'No (N)'	System	06 Oct 2020 02:04:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:18', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c4fbd0c2-331a-4115-a915-470dc28f1793'	System	06 Oct 2020 02:04:24
User entered 'None (1)'	System	06 Oct 2020 02:04:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:21', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c4fbd0c2-331a-4115-a915-470dc28f1793' User entered '05 Oct 2020 22:04'	System	06 Oct 2020 02:04:24
	System	06 Oct 2020 02:04:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 14:18'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 2'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:10', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '826f7224-6cd3-4478-b78f-215114bed8ad'	System	06 Oct 2020 21:02:24
User entered 'None (1)'	System	06 Oct 2020 21:02:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:12', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '826f7224-6cd3-4478-b78f-215114bed8ad'	System	06 Oct 2020 21:02:24
User entered 'No (N)'	System	06 Oct 2020 21:02:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:14', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '826f7224-6cd3-4478-b78f-215114bed8ad'	System	06 Oct 2020 21:02:24
User entered 'No (N)'	System	06 Oct 2020 21:02:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '826f7224-6cd3-4478-b78f-215114bed8ad'	System	06 Oct 2020 21:02:24
User entered 'None (1)'	System	06 Oct 2020 21:02:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:22', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '826f7224-6cd3-4478-b78f-215114bed8ad' User entered '06 Oct 2020 17:02'	System	06 Oct 2020 21:02:24
	System	06 Oct 2020 21:02:24

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 3'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9046d2ac-36d5-45d1-8985-8c62d43d1f86'	System	07 Oct 2020 21:04:51
User entered 'None (1)'	System	07 Oct 2020 21:04:51

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9046d2ac-36d5-45d1-8985-8c62d43d1f86'	System	07 Oct 2020 21:04:51
User entered 'No (N)'	System	07 Oct 2020 21:04:51

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9046d2ac-36d5-45d1-8985-8c62d43d1f86'	System	07 Oct 2020 21:04:51
User entered 'No (N)'	System	07 Oct 2020 21:04:51

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:44', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9046d2ac-36d5-45d1-8985-8c62d43d1f86'	System	07 Oct 2020 21:04:51
User entered 'None (1)'	System	07 Oct 2020 21:04:51

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:47', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9046d2ac-36d5-45d1-8985-8c62d43d1f86' User entered '07 Oct 2020 17:04'	System	07 Oct 2020 21:04:51
	System	07 Oct 2020 21:04:51

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 4'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:21', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2f1db480-c87a-40fa-8e9f-846b83cdf8bc'	System	08 Oct 2020 21:03:40
User entered 'None (1)'	System	08 Oct 2020 21:03:40

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:24', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2f1db480-c87a-40fa-8e9f-846b83cdf8bc' User entered 'No (N)'	System	08 Oct 2020 21:03:40
	System	08 Oct 2020 21:03:40

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:26', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2f1db480-c87a-40fa-8e9f-846b83cdf8bc' User entered 'No (N)'	System	08 Oct 2020 21:03:40
	System	08 Oct 2020 21:03:40

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:28', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2f1db480-c87a-40fa-8e9f-846b83cdf8bc'	System	08 Oct 2020 21:03:40
User entered 'None (1)'	System	08 Oct 2020 21:03:40

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2f1db480-c87a-40fa-8e9f-846b83cdf8bc' User entered '08 Oct 2020 17:03'	System	08 Oct 2020 21:03:40
	System	08 Oct 2020 21:03:40

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 5'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ae4acd0d-2c7d-4f8a-9d5b-79d6d24c823b'	System	09 Oct 2020 19:34:48
User entered 'None (1)'	System	09 Oct 2020 19:34:48

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:39', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ae4acd0d-2c7d-4f8a-9d5b-79d6d24c823b' User entered 'No (N)'	System	09 Oct 2020 19:34:48
	System	09 Oct 2020 19:34:48

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:41', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ae4acd0d-2c7d-4f8a-9d5b-79d6d24c823b' User entered 'No (N)'	System	09 Oct 2020 19:34:48
	System	09 Oct 2020 19:34:48

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:43', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ae4acd0d-2c7d-4f8a-9d5b-79d6d24c823b'	System	09 Oct 2020 19:34:48
User entered 'None (1)'	System	09 Oct 2020 19:34:48

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:46', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ae4acd0d-2c7d-4f8a-9d5b-79d6d24c823b' User entered '09 Oct 2020 15:34'	System	09 Oct 2020 19:34:48
	System	09 Oct 2020 19:34:48

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 6'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:32', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '98b36c70-4c29-48d3-932b-7634b1be04cf' User entered 'None (1)'	System	10 Oct 2020 21:03:43
	System	10 Oct 2020 21:03:43

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:35', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '98b36c70-4c29-48d3-932b-7634b1be04cf' User entered 'No (N)'	System	10 Oct 2020 21:03:43
	System	10 Oct 2020 21:03:43

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '98b36c70-4c29-48d3-932b-7634b1be04cf' User entered 'No (N)'	System	10 Oct 2020 21:03:43
	System	10 Oct 2020 21:03:43

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '98b36c70-4c29-48d3-932b-7634b1be04cf' User entered 'None (1)'	System	10 Oct 2020 21:03:43
	System	10 Oct 2020 21:03:43

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:41', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '98b36c70-4c29-48d3-932b-7634b1be04cf' User entered '10 Oct 2020 17:03'	System	10 Oct 2020 21:03:43
	System	10 Oct 2020 21:03:43

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 7'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:23:59', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7e97a82c-8a05-4ed9-911d-37e596a1547f' User entered 'None (1)'	System	11 Oct 2020 21:24:18
	System	11 Oct 2020 21:24:18

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7e97a82c-8a05-4ed9-911d-37e596a1547f' User entered 'No (N)'	System	11 Oct 2020 21:24:18
	System	11 Oct 2020 21:24:18

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:03', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7e97a82c-8a05-4ed9-911d-37e596a1547f' User entered 'No (N)'	System	11 Oct 2020 21:24:18
	System	11 Oct 2020 21:24:18

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:04', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7e97a82c-8a05-4ed9-911d-37e596a1547f' User entered 'None (1)'	System	11 Oct 2020 21:24:18
	System	11 Oct 2020 21:24:18

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7e97a82c-8a05-4ed9-911d-37e596a1547f' User entered '11 Oct 2020 17:24'	System	11 Oct 2020 21:24:18
	System	11 Oct 2020 21:24:18

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:49', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'None (0)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'None (0)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:53', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'None (0)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'None (0)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:57', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'None (0)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:14:59', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'None (0)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:15:04', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered 'No (N)'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T11:15:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'ebd08529-26f4-43e5-bcb7-7250e190e313' User entered '05 Oct 2020 11:15'	System	05 Oct 2020 15:15:11
	System	05 Oct 2020 15:15:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 10:53'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 13:23'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:25', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'None (0)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:29', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'None (0)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:31', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'None (0)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'None (0)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:35', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'None (0)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'None (0)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:39', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered 'No (N)'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-05T22:04:44', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4eea0cca-fa27-4aa6-8822-0ed73f8afcc9' User entered '05 Oct 2020 22:04'	System	06 Oct 2020 02:04:46
	System	06 Oct 2020 02:04:46

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '05 Oct 2020 14:18'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 2'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:26', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106'	System	06 Oct 2020 21:02:44
User entered 'None (0)'	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:27', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106'	System	06 Oct 2020 21:02:44
User entered 'None (0)'	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:30', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106'	System	06 Oct 2020 21:02:44
User entered 'None (0)'	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106' User entered 'None (0)'	System	06 Oct 2020 21:02:44
	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:34', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106'	System	06 Oct 2020 21:02:44
User entered 'None (0)'	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:36', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106'	System	06 Oct 2020 21:02:44
User entered 'None (0)'	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:39', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106'	System	06 Oct 2020 21:02:44
User entered 'No (N)'	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-06T17:02:43', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '107b0f30-9a47-4e78-93c8-1f81401e3106' User entered '06 Oct 2020 17:02'	System	06 Oct 2020 21:02:44
	System	06 Oct 2020 21:02:44

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 3'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'None (0)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:52', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'None (0)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:54', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'None (0)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:57', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'None (0)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:04:59', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'None (0)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:05:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'None (0)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:05:04', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered 'No (N)'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-07T17:05:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '1de1df1e-91ea-4a0a-ba1a-374f51ddbcc3' User entered '07 Oct 2020 17:05'	System	07 Oct 2020 21:05:11
	System	07 Oct 2020 21:05:11

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 4'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:37', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'None (0)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:38', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'None (0)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'None (0)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'None (0)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:43', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'None (0)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:45', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'None (0)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:48', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered 'No (N)'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-08T17:03:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '79ed16c7-ddd2-4a08-9268-6301f464e501' User entered '08 Oct 2020 17:03'	System	08 Oct 2020 21:03:58
	System	08 Oct 2020 21:03:58

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 5'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:49', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2' User entered 'None (0)'	System	09 Oct 2020 19:35:05
	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2'	System	09 Oct 2020 19:35:05
User entered 'None (0)'	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:53', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2'	System	09 Oct 2020 19:35:05
User entered 'None (0)'	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:55', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2'	System	09 Oct 2020 19:35:05
User entered 'None (0)'	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:56', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2' User entered 'None (0)'	System	09 Oct 2020 19:35:05
	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:34:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2'	System	09 Oct 2020 19:35:05
User entered 'None (0)'	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:35:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2'	System	09 Oct 2020 19:35:05
User entered 'No (N)'	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-09T15:35:03', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3861836d-1036-4a0f-afce-242c51710aa2' User entered '09 Oct 2020 15:35'	System	09 Oct 2020 19:35:05
	System	09 Oct 2020 19:35:05

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 6'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:46', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'None (0)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:48', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'None (0)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:49', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'None (0)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:51', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'None (0)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:03:54', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'None (0)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:04:02', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'None (0)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:04:05', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered 'No (N)'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-10T17:04:08', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f3262a3c-ea9d-4d9d-9945-006287f1c6e5' User entered '10 Oct 2020 17:04'	System	10 Oct 2020 21:04:09
	System	10 Oct 2020 21:04:09

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	05 Oct 2020 14:41:25
User entered 'Day 7'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'None (0)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:19', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'None (0)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:21', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'None (0)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:22', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'None (0)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:24', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'None (0)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:30', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'None (0)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

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)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered 'No (N)'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-10-11T17:24:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'eaea6050-28fe-4c5e-96c3-d641531a0603' User entered '11 Oct 2020 17:24'	System	11 Oct 2020 21:24:41
	System	11 Oct 2020 21:24:41

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 14:41:25

US3712013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:20:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 14:41:25

US3712013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:38:37

US3712013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:38:37

US3712013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:38:37

US3712013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:38:37

US3712013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:38:39

US3712013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	19 Oct 2020 21:38:39

US3712013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:26

US3712013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:26

US3712013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:26

US3712013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:26

US3712013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:28

US3712013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	27 Oct 2020 19:48:28

US3712013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24

US3712013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24

US3712013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24

US3712013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24

US3712013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:26

US3712013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'I'	System	03 Nov 2020 14:21:26

US3712013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:37

US3712013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:37

US3712013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:37

US3712013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'VISIT3'	System	09 Nov 2020 20:31:37

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered empty.	System	09 Nov 2020 20:31:45

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50

US3712013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50

US3712013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:48

US3712013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:48

US3712013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:34:30

US3712013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:34:30

US3712013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered '10:27'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:34:30

US3712013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '03 Nov 2020 10:27'	System	09 Nov 2020 20:34:30

US3712013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 20:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:31:29

US3712013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered '1'	System	09 Nov 2020 20:31:29

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 64'	System	08 Sep 2020 16:32:42

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-08T09:34:24', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b7955e65-086b-40b0-91c7-2c6ac1a46d0a'	System	08 Nov 2020 14:34:38
User entered 'No (N)'	System	08 Nov 2020 14:34:38

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-08T09:34:26', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b7955e65-086b-40b0-91c7-2c6ac1a46d0a'	System	08 Nov 2020 14:34:38
User entered 'No (N)'	System	08 Nov 2020 14:34:38

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-08T09:34:32', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'b7955e65-086b-40b0-91c7-2c6ac1a46d0a' User entered '08 Nov 2020 09:34:32'	System	08 Nov 2020 14:34:38
	System	08 Nov 2020 14:34:38

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 16:32:42

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered 'Day 71'	System	08 Sep 2020 16:32:42

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:25:49
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'medication added' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 21:34:38
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Dec 2020 16:02:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-15T08:04:48', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3fa9c5ee-e2fd-4ae2-b5a1-6f9443cfe9ae'	System	15 Nov 2020 13:05:27
User entered 'Yes (Y)'	System	15 Nov 2020 13:05:27

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-15T08:04:50', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3fa9c5ee-e2fd-4ae2-b5a1-6f9443cfe9ae'	System	15 Nov 2020 13:05:27
User entered 'No (N)'	System	15 Nov 2020 13:05:27

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-15T08:04:53', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3fa9c5ee-e2fd-4ae2-b5a1-6f9443cfe9ae'	System	15 Nov 2020 13:05:27
User entered 'No (N)'	System	15 Nov 2020 13:05:27

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-15T08:05:02', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3fa9c5ee-e2fd-4ae2-b5a1-6f9443cfe9ae'	System	15 Nov 2020 13:05:27
User entered 'Yes (Y)'	System	15 Nov 2020 13:05:27

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-15T08:05:09', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3fa9c5ee-e2fd-4ae2-b5a1-6f9443cfe9ae'	System	15 Nov 2020 13:05:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 13:05:27

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-15T08:05:16', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '3fa9c5ee-e2fd-4ae2-b5a1-6f9443cfe9ae' User entered '15 Nov 2020 08:05:16'	System	15 Nov 2020 13:05:27
	System	15 Nov 2020 13:05:27

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 16:32:42

US3712013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:19:53
Data entry locked.	System	08 Sep 2020 16:32:42
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 16:32:42

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-22T22:01:04', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ca9377d-45cb-4fed-b565-6cd3e7945462'	System	23 Nov 2020 03:01:16
User entered 'No (N)'	System	23 Nov 2020 03:01:16

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-22T22:01:06', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ca9377d-45cb-4fed-b565-6cd3e7945462'	System	23 Nov 2020 03:01:16
User entered 'No (N)'	System	23 Nov 2020 03:01:16

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-22T22:01:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '0ca9377d-45cb-4fed-b565-6cd3e7945462'	System	23 Nov 2020 03:01:16
User entered '22 Nov 2020 22:01:13'	System	23 Nov 2020 03:01:16

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-26T08:33:50', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '70ed3f1f-94d1-41f4-b2b1-ba69a1043982'	System	26 Nov 2020 13:34:11
User entered 'No (N)'	System	26 Nov 2020 13:34:11

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-26T08:33:56', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '70ed3f1f-94d1-41f4-b2b1-ba69a1043982'	System	26 Nov 2020 13:34:11
User entered 'No (N)'	System	26 Nov 2020 13:34:11

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-11-26T08:34:06', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '70ed3f1f-94d1-41f4-b2b1-ba69a1043982'	System	26 Nov 2020 13:34:11
User entered '26 Nov 2020 08:34:06'	System	26 Nov 2020 13:34:11

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-03T08:02:31', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c14e1c2a-bac5-4cbc-b6de-90cc7b7877cc'	System	03 Dec 2020 13:02:44
User entered 'No (N)'	System	03 Dec 2020 13:02:44

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-03T08:02:34', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c14e1c2a-bac5-4cbc-b6de-90cc7b7877cc'	System	03 Dec 2020 13:02:44
User entered 'No (N)'	System	03 Dec 2020 13:02:44

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-03T08:02:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'c14e1c2a-bac5-4cbc-b6de-90cc7b7877cc' User entered '03 Dec 2020 08:02:42'	System	03 Dec 2020 13:02:44
	System	03 Dec 2020 13:02:44

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-10T10:47:20', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '5ed19ad5-86a2-4493-92f2-25ee0b55d644'	System	10 Dec 2020 16:47:33
User entered 'No (N)'	System	10 Dec 2020 16:47:33

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-10T10:46:59', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '5ed19ad5-86a2-4493-92f2-25ee0b55d644'	System	10 Dec 2020 16:47:33
User entered 'No (N)'	System	10 Dec 2020 16:47:33

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-10T10:47:28', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '5ed19ad5-86a2-4493-92f2-25ee0b55d644'	System	10 Dec 2020 16:47:33
User entered '10 Dec 2020 10:47:28'	System	10 Dec 2020 16:47:33

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-17T09:00:57', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '038e949c-579e-4a4b-9480-6e788c3f9b95'	System	17 Dec 2020 14:01:09
User entered 'No (N)'	System	17 Dec 2020 14:01:09

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-17T09:01:01', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '038e949c-579e-4a4b-9480-6e788c3f9b95'	System	17 Dec 2020 14:01:09
User entered 'No (N)'	System	17 Dec 2020 14:01:09

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-17T09:01:05', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '038e949c-579e-4a4b-9480-6e788c3f9b95'	System	17 Dec 2020 14:01:09
User entered '17 Dec 2020 09:01:05'	System	17 Dec 2020 14:01:09

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-24T09:01:39', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6629ddb9-4e97-47a6-a62c-0d34f85dfb1e' User entered 'No (N)'	System	24 Dec 2020 14:01:50
	System	24 Dec 2020 14:01:50

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-24T09:01:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6629ddb9-4e97-47a6-a62c-0d34f85dfb1e' User entered 'No (N)'	System	24 Dec 2020 14:01:50
	System	24 Dec 2020 14:01:50

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-24T09:01:47', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '6629ddb9-4e97-47a6-a62c-0d34f85dfb1e' User entered '24 Dec 2020 09:01:47'	System	24 Dec 2020 14:01:50
	System	24 Dec 2020 14:01:50

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-31T19:19:54', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4987e916-4812-4010-aa88-c3e665972ec7'	System	01 Jan 2021 00:20:32
User entered 'Yes (Y)'	System	01 Jan 2021 00:20:32

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-31T19:20:15', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4987e916-4812-4010-aa88-c3e665972ec7'	System	01 Jan 2021 00:20:32
User entered 'No (N)'	System	01 Jan 2021 00:20:32

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-31T19:20:19', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4987e916-4812-4010-aa88-c3e665972ec7'	System	01 Jan 2021 00:20:32
User entered 'No (N)'	System	01 Jan 2021 00:20:32

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-31T19:20:23', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4987e916-4812-4010-aa88-c3e665972ec7'	System	01 Jan 2021 00:20:32
User entered 'No (N)'	System	01 Jan 2021 00:20:32

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2020-12-31T19:20:30', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '4987e916-4812-4010-aa88-c3e665972ec7'	System	01 Jan 2021 00:20:32
User entered '31 Dec 2020 19:20:30'	System	01 Jan 2021 00:20:32

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-08T17:02:09', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8758313a-a237-45bd-a1f4-e283345b6760'	System	08 Jan 2021 22:02:20
User entered 'No (N)'	System	08 Jan 2021 22:02:20

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-08T17:02:11', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8758313a-a237-45bd-a1f4-e283345b6760'	System	08 Jan 2021 22:02:20
User entered 'No (N)'	System	08 Jan 2021 22:02:20

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-08T17:02:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8758313a-a237-45bd-a1f4-e283345b6760'	System	08 Jan 2021 22:02:20
User entered '08 Jan 2021 17:02:17'	System	08 Jan 2021 22:02:20

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-16T12:00:35', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8bc18809-5b19-4b0c-8248-823c6573b661'	System	16 Jan 2021 17:01:55
User entered 'No (N)'	System	16 Jan 2021 17:01:55

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-16T12:00:40', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8bc18809-5b19-4b0c-8248-823c6573b661'	System	16 Jan 2021 17:01:55
User entered 'No (N)'	System	16 Jan 2021 17:01:55

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-16T12:00:44', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '8bc18809-5b19-4b0c-8248-823c6573b661'	System	16 Jan 2021 17:01:55
User entered '16 Jan 2021 12:00:44'	System	16 Jan 2021 17:01:55

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-23T12:49:26', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '78abaeaa-d82d-41cc-8827-305d0e460c45'	System	23 Jan 2021 17:49:46
User entered 'No (N)'	System	23 Jan 2021 17:49:46

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-23T12:49:33', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '78abaeaa-d82d-41cc-8827-305d0e460c45'	System	23 Jan 2021 17:49:46
User entered 'No (N)'	System	23 Jan 2021 17:49:46

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-23T12:49:42', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '78abaeaa-d82d-41cc-8827-305d0e460c45' User entered '23 Jan 2021 12:49:42'	System	23 Jan 2021 17:49:46
	System	23 Jan 2021 17:49:46

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-30T12:01:13', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '09216cd2-151c-47fa-b81c-217ac1f87274' User entered 'No (N)'	System	30 Jan 2021 17:04:29
	System	30 Jan 2021 17:04:29

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-30T12:01:16', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '09216cd2-151c-47fa-b81c-217ac1f87274'	System	30 Jan 2021 17:04:29
User entered 'No (N)'	System	30 Jan 2021 17:04:29

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-01-30T12:01:22', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '09216cd2-151c-47fa-b81c-217ac1f87274' User entered '30 Jan 2021 12:01:22'	System	30 Jan 2021 17:04:29
	System	30 Jan 2021 17:04:29

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-06T16:06:12', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '64b3104b-16a9-4ebb-a47e-dc56df0f36dd'	System	06 Feb 2021 21:06:25
User entered 'No (N)'	System	06 Feb 2021 21:06:25

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-06T16:06:17', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '64b3104b-16a9-4ebb-a47e-dc56df0f36dd'	System	06 Feb 2021 21:06:25
User entered 'No (N)'	System	06 Feb 2021 21:06:25

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-06T16:06:20', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '64b3104b-16a9-4ebb-a47e-dc56df0f36dd'	System	06 Feb 2021 21:06:25
User entered '06 Feb 2021 16:06:20'	System	06 Feb 2021 21:06:25

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-11T09:00:21', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a27a6139-5401-47ad-8a12-ac67b1d3ddb2'	System	11 Feb 2021 14:00:38
User entered 'No (N)'	System	11 Feb 2021 14:00:38

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-11T09:00:25', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a27a6139-5401-47ad-8a12-ac67b1d3ddb2'	System	11 Feb 2021 14:00:38
User entered 'No (N)'	System	11 Feb 2021 14:00:38

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-11T09:00:31', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'a27a6139-5401-47ad-8a12-ac67b1d3ddb2'	System	11 Feb 2021 14:00:38
User entered '11 Feb 2021 09:00:31'	System	11 Feb 2021 14:00:38

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-18T21:51:58', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '24526ca9-2f11-46ef-b92b-31971c4d6aca'	System	19 Feb 2021 02:52:30
User entered 'No (N)'	System	19 Feb 2021 02:52:30

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-18T21:52:02', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '24526ca9-2f11-46ef-b92b-31971c4d6aca' User entered 'No (N)'	System	19 Feb 2021 02:52:30
	System	19 Feb 2021 02:52:30

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-18T21:52:24', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '24526ca9-2f11-46ef-b92b-31971c4d6aca' User entered '18 Feb 2021 21:52:24'	System	19 Feb 2021 02:52:30
	System	19 Feb 2021 02:52:30

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-25T13:00:21-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '430958ac-cf68-48fd-8714-ead3faf00350'	System	25 Feb 2021 18:19:59
User entered 'No (N)'	System	25 Feb 2021 18:19:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-25T13:00:27-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '430958ac-cf68-48fd-8714-ead3faf00350'	System	25 Feb 2021 18:19:59
User entered 'No (N)'	System	25 Feb 2021 18:19:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-25T13:00:32-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '430958ac-cf68-48fd-8714-ead3faf00350'	System	25 Feb 2021 18:19:59
User entered '25 Feb 2021 18:00:32'	System	25 Feb 2021 18:19:59

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-04T06:44:08-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '03511c4e-24a6-4413-9eed-358876f9fd3e'	System	04 Mar 2021 11:44:37
User entered 'No (N)'	System	04 Mar 2021 11:44:37

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-04T06:44:25-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '03511c4e-24a6-4413-9eed-358876f9fd3e'	System	04 Mar 2021 11:44:37
User entered 'No (N)'	System	04 Mar 2021 11:44:37

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-04T06:44:33-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '03511c4e-24a6-4413-9eed-358876f9fd3e' User entered '04 Mar 2021 06:44:33'	System	04 Mar 2021 11:44:37
	System	04 Mar 2021 11:44:37

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-11T05:57:26-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f46233b2-3c17-473a-b94f-373a04382006'	System	11 Mar 2021 10:57:42
User entered 'No (N)'	System	11 Mar 2021 10:57:42

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-11T05:57:31-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f46233b2-3c17-473a-b94f-373a04382006'	System	11 Mar 2021 10:57:42
User entered 'No (N)'	System	11 Mar 2021 10:57:42

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-11T05:57:39-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'f46233b2-3c17-473a-b94f-373a04382006' User entered '11 Mar 2021 05:57:39'	System	11 Mar 2021 10:57:42
	System	11 Mar 2021 10:57:42

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-18T09:32:47-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cf6709c7-5f3e-4bb1-9e64-4f0054ec55aa'	System	20 Mar 2021 12:53:56
User entered 'No (N)'	System	20 Mar 2021 12:53:56

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-18T09:32:51-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cf6709c7-5f3e-4bb1-9e64-4f0054ec55aa'	System	20 Mar 2021 12:53:56
User entered 'No (N)'	System	20 Mar 2021 12:53:56

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-18T09:32:57-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: 'cf6709c7-5f3e-4bb1-9e64-4f0054ec55aa' User entered '18 Mar 2021 09:32:57'	System	20 Mar 2021 12:53:56
	System	20 Mar 2021 12:53:56

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-25T21:36:16-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2490586c-298b-4075-9bc4-a1097b04d117'	System	26 Mar 2021 01:37:04
User entered 'No (N)'	System	26 Mar 2021 01:37:04

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-25T21:36:19-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2490586c-298b-4075-9bc4-a1097b04d117'	System	26 Mar 2021 01:37:04
User entered 'No (N)'	System	26 Mar 2021 01:37:04

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-03-25T21:36:25-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '2490586c-298b-4075-9bc4-a1097b04d117'	System	26 Mar 2021 01:37:04
User entered '25 Mar 2021 21:36:25'	System	26 Mar 2021 01:37:04

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-04-01T07:21:20-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9fea16f8-e79f-462a-8e47-bfc2b583203a' User entered 'No (N)'	System	01 Apr 2021 11:21:28
	System	01 Apr 2021 11:21:28

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-04-01T07:21:22-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9fea16f8-e79f-462a-8e47-bfc2b583203a'	System	01 Apr 2021 11:21:28
User entered 'No (N)'	System	01 Apr 2021 11:21:28

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-04-01T07:21:26-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '9fea16f8-e79f-462a-8e47-bfc2b583203a'	System	01 Apr 2021 11:21:28
User entered '01 Apr 2021 07:21:26'	System	01 Apr 2021 11:21:28

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-04-08T07:28:26-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '29eff713-3fe0-4278-977f-6ab4d582a522'	System	08 Apr 2021 11:28:33
User entered 'No (N)'	System	08 Apr 2021 11:28:33

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

Have you been exposed to someone with 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 (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-04-08T07:28:29-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '29eff713-3fe0-4278-977f-6ab4d582a522'	System	08 Apr 2021 11:28:33
User entered 'No (N)'	System	08 Apr 2021 11:28:33

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-04-08T07:28:31-04:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '29eff713-3fe0-4278-977f-6ab4d582a522'	System	08 Apr 2021 11:28:33
User entered '08 Apr 2021 07:28:31'	System	08 Apr 2021 11:28:33

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '10 Nov 2022 00:01'	System	19 Nov 2020 19:09:06

US3712013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:20:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:09:06
Amendment Manager: User entered '14 Nov 2022 23:59'	System	19 Nov 2020 19:09:06

US3712013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:20:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:43:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-28T18:15:54-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7c3352cb-ce53-4726-8025-938b902410cf'	System	04 Mar 2021 11:44:09
User entered 'No (N)'	System	04 Mar 2021 11:44:09

US3712013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:20:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:43:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A2ECBB6-4A96-4D49-9BF9-4D4F9F91A273)', Time: '2021-02-28T18:16:01-05:00', User OID: 'PatientReportedOutcome (US3712013)', ODM File OID: '7c3352cb-ce53-4726-8025-938b902410cf' User entered '28 Feb 2021 18:16:01'	System	04 Mar 2021 11:44:09
	System	04 Mar 2021 11:44:09

US3712013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:27:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:55:59

US3712013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:27:10
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:55:59

US3712013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:27:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:55:59

US3712013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:27:10
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:55:59

US3712013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:27:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:56:01

US3712013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:50
User entered 'I'	System	01 Dec 2020 21:56:01

US3712013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 26-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:51:07
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 26-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:35:24
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 26-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:23:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 16:27:07

US3712013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:27:07

US3712013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:27:07

US3712013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:27:07

US3712013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:27:09

US3712013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User entered '1'	System	19 Jan 2021 16:27:09

US3712013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:58:26

US3712013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:58:26

US3712013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:58:26

US3712013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:58:26

US3712013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:58:27

US3712013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User entered '1'	System	22 Feb 2021 21:58:27

US3712013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:47:19

US3712013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:47:19

US3712013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:47:19

US3712013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:47:19

US3712013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:47:22

US3712013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:16:33
User entered '1'	System	10 Mar 2021 18:47:22

US3712013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:14

US3712013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:14

US3712013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:14

US3712013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered 'VISIT4'	System	07 Apr 2021 13:34:14

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered empty.	System	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered empty.	System	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered empty.	System	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered empty.	System	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered empty.	System	07 Apr 2021 13:34:36

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02

US3712013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02

US3712013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:43

US3712013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:43

US3712013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:51

US3712013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:51

US3712013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered '09:19'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:51

US3712013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered '06 Apr 2021 09:19'	System	07 Apr 2021 13:34:51

US3712013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:08:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:34:53

US3712013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:39:02
User entered '1'	System	07 Apr 2021 13:34:53

US3712013

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

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:39

US3712013

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

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:39

US3712013

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

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:39

US3712013

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

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 14:35:39

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User entered '26 Jan 2021' reason for change: Data Entry Error	System	12 Mar 2021 21:40:01
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 21:40:01
User entered '26 Jun 2021' reason for change: Data Entry Error	System	12 Mar 2021 21:39:57
User entered '06 Jan 2021'	(b) (4), (b) (6)	12 Mar 2021 21:39:57
	(b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:07:03

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:07:03

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	12 Mar 2021 21:40:01
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '1'	System	03 Feb 2021 15:00:45

US3712013

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

Form: Unblinding

Generated On: 10 Jun 2021 09:20:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '1'	System	03 Feb 2021 15:00:45

US3712013

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered empty.	System	03 Feb 2021 15:01:32
DataPoint set to visible.	System	03 Feb 2021 15:00:45

US3712013

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered empty.	System	03 Feb 2021 15:01:32
DataPoint set to visible.	System	03 Feb 2021 15:00:45

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '09:28'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '26 Jan 2021 09:28'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '66'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'bpm'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '19'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'breaths/min'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '123'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'mmHg'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '77'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'mmHg'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:20:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered empty.	System	03 Feb 2021 15:01:32
DataPoint set to visible.	System	03 Feb 2021 15:00:45

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '10:34'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '26 Jan 2021 10:34'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '67'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'bpm'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'breaths/min'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '116'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'mmHg'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '69'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'mmHg'	System	03 Feb 2021 15:01:32

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:41

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:41

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

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)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'mRNA-1273'	System	03 Feb 2021 15:01:52
DataPoint set to visible.	System	03 Feb 2021 15:00:45

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).		12 Mar 2021 21:39:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '10:04'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '26 Jan 2021 10:04'	System	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'ONCE'	System	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 15:01:52

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:21

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:00:21

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '09:20'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:21

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '26 Jan 2021 09:20'	System	03 Feb 2021 15:00:21

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:28

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:00:28

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '09:22'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:00:28

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:20:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '26 Jan 2021 09:22'	System	03 Feb 2021 15:00:28

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 13:28:29

US3712013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:38
User entered '1'	System	24 Feb 2021 13:28:29

US3712013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:18

US3712013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '05 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 21:09:18

US3712013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:18

US3712013

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:18

US3712013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:21

US3712013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User entered '1'	System	02 Mar 2021 21:09:21

US3712013

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:08
User entered '1'	System	02 Mar 2021 21:09:21
DataPoint set to visible.	System	02 Mar 2021 21:09:21

US3712013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:46

US3712013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:46

US3712013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:09:46

US3712013

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'OLD29'	System	02 Mar 2021 21:09:46

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '23 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '09:04'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered '23 Feb 2021 09:04'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '57'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'bpm'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'breaths/min'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '110'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'mmHg'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '61'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'mmHg'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '23 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '10:36'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered '23 Feb 2021 10:36'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '56'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'bpm'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'breaths/min'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '120'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'mmHg'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '77'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'mmHg'	System	02 Mar 2021 21:10:31

US3712013

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:35

US3712013

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:35

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

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)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'mRNA-1273'	System	02 Mar 2021 21:10:45
DataPoint set to visible.	System	02 Mar 2021 21:09:21

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).		12 Mar 2021 21:39:57
User entered '23 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '10:05'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered '23 Feb 2021 10:05'	System	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'ONCE'	System	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:20:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 21:10:45

US3712013

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:10:51

US3712013

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:40:47
User entered '1'	System	02 Mar 2021 21:10:51

US3712013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:38:34
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 12:53:03

US3712013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:38:34
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:40:01
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:39:57
User entered '02 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 12:53:03

US3712013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:38:34
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 12:53:03

US3712013

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:20:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:38:34
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 12:53:03

US3712013

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:38:34
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 12:53:05

US3712013

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:20:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:38:34
User entered '1'	System	03 Mar 2021 12:53:05

US3712013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:22:39

US3712013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:22:39

US3712013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:22:39

US3712013

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:20:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered 'OLD57'	System	29 Mar 2021 14:22:39

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered empty.	System	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered empty.	System	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered empty.	System	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered empty.	System	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered empty.	System	29 Mar 2021 14:28:04

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32

US3712013

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:20:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32

US3712013

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:07

US3712013

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:20:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:07

US3712013

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:14

US3712013

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:14

US3712013

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '09:17'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:28:14

US3712013

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:20:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:27:32
User entered '26 Mar 2021 09:17'	System	29 Mar 2021 14:28:14

US3712013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:20:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:48:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:41
User signature succeeded.	William Smith (b) (4)	12 Mar 2021 22:17:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:52:04
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 13:30:11

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:24:27
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
User entered 'USA-US068-2021-mRNA-1273-P301000017'	(b) (4) System	05 Mar 2021 17:19:46
User entered 'New'	(b) (4), (b) (6)	05 Mar 2021 17:19:46

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4)	04 Mar 2021 21:34:31
	(b) (4), (b) (6)	
User closed query 'Please confirm, how long was patient in hospital? ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 20:49:57
Query 'Please confirm, how long was patient in hospital? ' answered with 'Stayed over night. SAE written up' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 19:51:02
User opened query 'Please confirm, how long was patient in hospital? ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:24:26
User closed query 'Per MM, this subject presented with pneumonia - please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:52:20
Query 'Per MM, this subject presented with pneumonia - please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'COVID-19 test completed at outside facility - negative' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:39:59
User opened query 'Per MM, this subject presented with pneumonia - please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 01:51:35
User closed query 'Per MM, this subject presented pneumonia - please confirm if this subject was assessed for potential COVID-19 infection for the evaluation of the Primary Efficacy Endpoint.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:21:03
Query 'Per MM, this subject presented pneumonia - please confirm if this subject was assessed for potential COVID-19 infection for the evaluation of the Primary Efficacy Endpoint.' answered with 'subject was assessed for potential COVID-19 during hospital visit' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 18:08:53
User opened query 'Per MM, this subject presented pneumonia - please confirm if this subject was assessed for potential COVID-19 infection for the evaluation of the Primary Efficacy Endpoint.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 13:07:50

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 20:54:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 20:54:39
Data point term sent to Coder	System	24 Sep 2020 20:53:45
User entered 'Pneumonia'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
User closed query 'PV Query: Please confirm the event onset date. It was reported as 18 Sep 2020, however, on 19 Sep 2020, the subject had pain in the left side, chest, and back.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:45:53
Query 'PV Query: Please confirm the event onset date. It was reported as 18 Sep 2020, however, on 19 Sep 2020, the subject had pain in the left side, chest, and back.' answered with 'start date is correct, 18 September 2020' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 19:03:55
User opened query 'PV Query: Please confirm the event onset date. It was reported as 18 Sep 2020, however, on 19 Sep 2020, the subject had pain in the left side, chest, and back.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:37:06
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:38:15
User entered '19 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Sep 2020 20:53:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:12
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Sep 2020 20:52:58
User entered '14:00'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 20:53:12
User entered '19 Sep 2020 14:00'	System	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:42:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:42:48
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
Query 'Per MM, Please provide end date and final outcome when available.' canceled (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 13:08:13
User opened query 'Per MM, Please provide end date and final outcome when available.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 13:08:10
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 20:52:58

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:38:15
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

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Death

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	04 Mar 2021 19:51:51
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	04 Mar 2021 19:51:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	04 Mar 2021 19:38:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:38:15
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
User closed query 'PV Query: Please clarify/confirm the hospital admission and discharge dates. It was reported the subject was advised to go to the hospital on 22 Sep 2020, however, hospital admission was reported as 21 Sep 2020. Hospital discharge date was reported as 22 Sep 2020 (the day the subject was advised to go to the hospital)' (Site from Safety). Query 'PV Query: Please clarify/confirm the hospital admission and discharge dates. It was reported the subject was advised to go to the hospital on 22 Sep 2020, however, hospital admission was reported as 21 Sep 2020. Hospital discharge date was reported as 22 Sep 2020 (the day the subject was advised to go to the hospital)' answered with 'hospital admission date is correct, 21 September 2020 and was discharged the next day on 22 September 2020' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:45:58
User opened query 'PV Query: Please clarify/confirm the hospital admission and discharge dates. It was reported the subject was advised to go to the hospital on 22 Sep 2020, however, hospital admission was reported as 21 Sep 2020. Hospital discharge date was reported as 22 Sep 2020 (the day the subject was advised to go to the hospital)' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 19:05:18
User opened query 'PV Query: Please clarify/confirm the hospital admission and discharge dates. It was reported the subject was advised to go to the hospital on 22 Sep 2020, however, hospital admission was reported as 21 Sep 2020. Hospital discharge date was reported as 22 Sep 2020 (the day the subject was advised to go to the hospital)' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:37:26
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:38:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:38:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:51:51
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

US3712013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:42:42
User closed query 'Please confirm, if this should be reflected on the paper source for this event. if so, please update' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 18:42:39
Query 'Please confirm, if this should be reflected on the paper source for this event. if so, please update' answered with 'unmarked ' (Site from CRA).	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 19:07:56
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:07:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:34:31
User opened query 'Please confirm, if this should be reflected on the paper source for this event. if so, please update' (Site from CRA). User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:33:17
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 19:51:26
	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4)	04 Mar 2021 21:34:31
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:53:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:53:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:52:58
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:53:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:53:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:52:58
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:53:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:53:25
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:53:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:52:58
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

None

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:42:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:34:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:12
User closed query 'Please review dates, as it seems subject was referred by PCP to go to ED on 21Sep2020. Also, it seems this event started on 18Sep, not 19Sep. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 18:43:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 15:26:40
User signature succeeded.	William Smith (b) (4)	18 Mar 2021 22:14:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'email sent with relevant laboratory and diagnostic test results on March 16' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:25:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED STAFF DURING HIS DAY 15 PHONE CALL ON 22 SEPTEMBER 2020 THAT HE WAS IN THE HOSPITAL. ON 18 SEPTEMBER 2020 SUBJECT STATED HAVING PAIN IN THEIR LEFT SIDE, CHEST AND BACK. ON 21 SEPTEMBER 2020 SUBJECT WAS ADVISED BY PCP TO GO TO THE HOSPITAL. UPON ARRIVAL TO ED SUBJECT HAS EKG, CHEST X-RAY, AND CT SCAN DONE. CT SCAN SHOWED PNEUMONIA IN LEFT LUNG. COVID-19 TEST WAS OBTAINED AND RESULTED NEGATIVE. SUBJECT PRESCRIBED DOXYCYCLINE 100MG TAB BID X 4 DAYS AND CEFDINIR 300MG TAB BID X 4 DAYS. CT THORAX: MEDICAL LEFT LOWER LOBE OPACITY IS AT LEAST PARTIALLY ATELECTATIC ALTHOUGH CANNOT EXCLUDE DEVELOPING PNEUMONIA. TRACE LEFT PLEURAL EFFUSION. RIGHT DIAPHRAGMATIC EVENTRATION AND ADJACENT ATELECTASIS. EKG: NORMAL CHEST X-RAY: ELEVATED RIGHT HEMIDIAPHRAGM NO CONGESTION AND NO PNEUMOTHORAX.' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:33
Query 'Please review dates, as it seems subject was referred by PCP to go to ED on 21Sep2020. Also, it seems this event started on 18Sep, not 19Sep. ' answered with 'updated' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 19:09:54
	(b) (4), (b) (6)	15 Mar 2021 19:09:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTIFIED STAFF DURING HIS DAY 15 PHONE CALL ON 22 SEPTEMBER 2020 THAT HE WAS IN THE HOSPITAL. ON 18 SEPTEMBER 2020 SUBJECT STATED HAVING PAIN IN THEIR LEFT SIDE, CHEST AND BACK. ON 22 SEPTEMBER 2020 SUBJECT WAS ADVISED BY PCP TO GO TO THE HOSPITAL. UPON ARRIVAL TO ED SUBJECT HAS EKG, CHEST X-RAY, AND CT SCAN DONE. CT SCAN SHOWED PNEUMONIA IN LEFT LUNG. COVID-19 TEST WAS OBTAINED AND RESULTED NEGATIVE. SUBJECT PRESCRIBED DOXYCYCLINE 100MG TAB BID X 4 DAYS AND CEFDINIR 300MG TAB BID X 4 DAYS. CT THORAX: MEDICAL LEFT LOWER LOVE OPACITY IS AT LEAST PARTIALLY ATELECTATIC ALTHOUGH CANNOT EXCLUDE DEVELOPING PNEUMONIA. TRACE LEFT PLEURAL EFFUSION. RIGHT DIAPHRAGMATIC EVENTRATION AND ADJACENT ATELECTASIS. EKG: NORMAL CHEST X-RAY: ELEVATED RIGHT HEMIDIAPHRAGM NO CONGESTION AND NO PNEUMOTHORAX.' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:09:46
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:38:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:34:31
User opened query 'Please review dates, as it seems subject was referred by PCP to go to ED on 21Sep2020. Also, it seems this event started on 18Sep, not 19Sep. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 21:34:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject notified staff during his day 15 phone call on 22 September 2020 that he was in the hospital. On 19 September 2020 subject stated having pain in their left side, chest and back. On 22 September 2020 subject was advised by PCP to go to the hospital. Upon arrival to ED subject has EKG, chest x-ray, and CT scan done. CT scan showed pneumonia in left lung. COVID-19 test was obtained and resulted negative. Subject prescribed Doxycycline 100mg tab BID x 4 days and Cefdinir 300mg tab BID x 4 days. CT thorax: Medical left lower love opacity is at least partially atelectatic although cannot exclude developing pneumonia. Trace left pleural effusion. Right diaphragmatic eventration and adjacent atelectasis. EKG: normal Chest x-ray: Elevated right hemidiaphragm no congestion and no pneumothorax.'	(b) (4), (b) (6)	04 Mar 2021 19:38:15
reason for change: Data Entry Error User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:20:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 19:38:15
User entered '0'	System	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 20:52:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 19:51:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:20:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:48:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:22:22

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:26:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:26:52
Data point term sent to Coder User entered 'flonase'	System (b) (4), (b) (6)	08 Sep 2020 20:26:04 08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Seasonal allergies'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:35:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '50'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:05:51
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:40:02
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 12:39:40
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:55:56
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 12:39:40
User entered 'Microgram'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2016'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:25:58

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:27:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:27:52
Data point term sent to Coder	System	08 Sep 2020 20:27:08
User entered 'famotidine'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Acid reflux'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '20'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:36:02
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:37:00
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 12:36:54
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:11:56
User entered 'un UNK 2005'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:26:51

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:28:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:28:52
Data point term sent to Coder	System	08 Sep 2020 20:28:10
User entered 'Fish Oil'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Supplement'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '1400'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2010'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:28:09

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:29:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:29:52
Data point term sent to Coder	System	08 Sep 2020 20:29:10
User entered 'vitamin D3'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Supplement'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '1000'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'IU (IU)'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2010'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:28:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:51:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:51:55
Data point term sent to Coder	System	08 Sep 2020 20:33:27
User entered 'Folic acid (tablet)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:52:54
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' answered with 'data updated per query response' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:01:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 13:00:53
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 09:03:30
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Supplement'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '400'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:06:02
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:40:33
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 12:40:25
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:56:14
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 12:40:25
User entered 'microgram'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2010'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:32:26

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:33:53
Data point term sent to Coder User entered 'Niacin'	System (b) (4), (b) (6)	08 Sep 2020 20:33:28 08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Supplement'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '1000'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2010'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:33:08

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:35:21
Data point term sent to Coder	System	08 Sep 2020 20:34:30
User entered 'pantoprazole'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Acid reflux'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '40'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:36:10
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:38:12
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 12:38:04
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:12:24
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 20:36:01
User entered 'un UNK 2016'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:34:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:36:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:36:53
Data point term sent to Coder	System	08 Sep 2020 20:35:32
User entered 'vitamin B12'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:53:46
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' answered with 'data updated per ECCGS' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:17:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 13:17:01
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 09:05:01
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Supplement'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '1000'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:06:14
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:40:59
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 12:40:51
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:56:31
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 12:40:51
User entered 'Microgram'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2010'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:35:15

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:37:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:37:56
Data point term sent to Coder User entered 'Allegra'	System (b) (4), (b) (6)	08 Sep 2020 20:36:32 08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Seasonal allergies'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '180'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2019'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:35:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:40:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:40:51
Data point term sent to Coder	System	08 Sep 2020 20:39:37
User entered 'Benadryl'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Insomnia'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '80'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'un UNK 2019'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:38:43

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:01:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:01:35
Data point term sent to Coder	System	16 Sep 2020 15:13:17
User closed query 'CDM-Coding: The trade name TUMS can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.' (Site from System).	System	16 Sep 2020 15:13:03
Query 'CDM-Coding: The trade name TUMS can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.' answered with 'Added active ingredient ' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 15:13:03
User entered 'TUMS (Calcium Carbonate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 15:12:47
User opened query 'CDM-Coding: The trade name TUMS can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4) (b) (4)	15 Sep 2020 10:26:35
Data point term sent to Coder	System	08 Sep 2020 20:40:38
User entered 'Tums (chewable)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Acid reflux'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:36:19
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:40:20
User entered '2000' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 12:40:14
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:12:50
User entered '2-4'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 12:40:14
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:36:28
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:46:38
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:12:59
User entered 'un UNK 1990'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 20:39:52

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:49:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:49:41
Data point term sent to Coder	System	24 Sep 2020 20:54:45
User entered 'Doxycycline'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Pneumonia'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '100'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'twice daily (BID)'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:44:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:44:35
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 20:54:32

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:24:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:24:41
Data point term sent to Coder	System	24 Sep 2020 20:55:46
User entered 'Cefdinir'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Pneumonia'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '300'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'twice daily (BID)'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:44:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 14:44:49
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 20:55:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:25:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:25:50
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:17:16
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 Oct 2020 15:17:16
Data point term sent to Coder	System	05 Oct 2020 14:47:14
User entered 'sodium chloride'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '10'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:46:17

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:27:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:27:23
Data point term sent to Coder	System	29 Jan 2021 19:39:02
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 19:38:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:44:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:44:00
Data point term sent to Coder	System	04 Dec 2020 14:31:30
Coding entries removed.	(b) (4), (b) (6)	04 Dec 2020 14:30:30

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:48:23
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 Oct 2020 14:48:23
Data point term sent to Coder	System	05 Oct 2020 14:47:17
User entered 'aspirin'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:04:51
User closed query 'Per DM CLR: After reviewing the indication of this medication, and if applicable, please specify if the NON-CARDIAC CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:54:37
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'CONFIRMED' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:40:19
Query 'Per DM CLR: After reviewing the indication of this medication, and if applicable, please specify if the NON-CARDIAC CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:39:04
User entered 'generalized NON-CARDIAC CHEST PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 19:38:55
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:25:22

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: After reviewing the indication of this medication, and if applicable, please specify if the NON-CARDIAC CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:25:06
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 15:08:12
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'corrected. related to pneumonia' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:30:40
User entered 'non-cardiac CHEST PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 14:30:30
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:06:23
User entered 'chest pain'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '325'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:46:50

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:00:25
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 Oct 2020 15:00:25
Data point term sent to Coder	System	05 Oct 2020 14:48:19
User entered 'ceftriaxone'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '2'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'g (g)'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 14:47:46

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 15 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: this Con Med was added/ had dose increased on 15 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.'	(b) (4), (b) (6)	04 Feb 2021 16:12:46
answered with 'Just started taking a new medication, no worsening ' (Site from DM). User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 15 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:34:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	22 Dec 2020 02:29:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:34:39
Data point term sent to Coder User entered 'cetirizine hydrochloride'	System (b) (4), (b) (6)	09 Nov 2020 20:33:59 09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'seasonal allergies'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '10'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '15 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 20:33:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
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)	19 Nov 2020 11:10:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:10:58
Data point term sent to Coder	System	09 Nov 2020 20:34:00
User entered 'influenza vaccine'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'influenza preventive'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:39:54
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:42:32
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 19:42:26
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 02:28:07
User entered '5'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mL (mL)'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once (ONCE)'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:33:55

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:59:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:59:45
Data point term sent to Coder	System	03 Feb 2021 14:58:59
User entered 'atorvastatin'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'hyperlipidemia'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '20'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '15 Nov 2020'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 14:58:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:00:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:00:45
Data point term sent to Coder User entered 'aspirin'	System (b) (4), (b) (6)	03 Feb 2021 15:00:00 03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'cardiac prophylaxis'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '81'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '15 Nov 2020'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 14:59:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:00:44
Data point term sent to Coder	System	03 Feb 2021 15:00:00
User entered 'melatonin'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'insomnia'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '10'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '31 Dec 2020'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 14:59:57

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
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)	04 Mar 2021 20:38:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:38:03
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)	04 Mar 2021 20:22:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:22:19
Data point term sent to Coder User entered 'acetaminophen'	System (b) (4), (b) (6)	04 Mar 2021 20:21:35 04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia inpatient treatment'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '650'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:21:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	07 Mar 2021 22:34:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 22:34:54
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:12:31
Data point term sent to Coder	System	04 Mar 2021 20:21:35
User entered 'lovenox'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia inpatient treatment'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '40'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:21:29

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:26:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:26:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:12:31
Data point term sent to Coder	System	04 Mar 2021 20:22:36
User entered 'melatonin'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia inpatient treatment '	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '5'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:22:21

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:08:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:08:54
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:12:31
Data point term sent to Coder	System	04 Mar 2021 20:27:45
User entered 'ondansetron'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia inpatient treatment '	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '4'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:27:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 21:03:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 21:03:40
Data point term sent to Coder	System	04 Mar 2021 20:30:54
User entered 'famotidine'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'PNEUMONIA inpatient treatment '	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '20'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:30:03

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:08:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:08:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:12:31
Data point term sent to Coder	System	04 Mar 2021 20:28:51
User entered 'ondansetron'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4)	04 Mar 2021 21:12:31
	(b) (4), (b) (6)	
User entered 'PNEUMONIA inpatient treatment'	(b) (4), (b) (6)	04 Mar 2021 20:28:18
reason for change: Data Entry Error		
User entered 'pneumonia '	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '4'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:28:00

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:49:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:49:09
Data point term sent to Coder	System	04 Mar 2021 20:31:59
User entered 'fexofenadine'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia inpatient treatment'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '180'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:31:13

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: SILDENAFIL CITRATE, PRODUCTSYNONYM: REVATIO - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 10:43:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:43:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:12:31
Data point term sent to Coder User entered 'revatio'	System (b) (4), (b) (6)	04 Mar 2021 20:32:01 04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'pneumonia inpatient treatment'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '20'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '21 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '0'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered '22 Sep 2020'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:31
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:31:47

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: DIPHTHERIA TETANUS PERTUSSIS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:59:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:59:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:52:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: DIPHTHERIA VACCINE;TETANUS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:28:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:28:32
Data point term sent to Coder	System	29 Mar 2021 14:32:20
User entered 'tetanus diphtheria vaccine'	(b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'tetanus prophylaxis'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '0.5'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:28
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:20:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:32:19

US3712013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:20:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:07:14

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:10
User entered 'USA-US068-2021-MRNA-1273-P301000017'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Un-reviewed for Safety.	(b) (4)	15 Mar 2021 19:07:20
User entered 'No (N)'	System	15 Mar 2021 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'William'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Smith'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered (b) (4)	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'US'	(b) (4) System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 13:46:16
User entered '1'	System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:10
User entered 'USA-US068-2021-MRNA-1273-P301000017'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Un-reviewed for Safety.	(b) (4)	15 Mar 2021 19:07:20
User entered 'No (N)'	System	15 Mar 2021 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'William'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Smith'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered (b) (4) '	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'US'	(b) (4) System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 13:46:16
User entered '1'	System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:20:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '05/Mar/2021 12:20'	(b) (4) System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:20:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:10
User entered 'USA-US068-2021-MRNA-1273-P301000017'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'No (N)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Un-reviewed for Safety.	(b) (4)	15 Mar 2021 19:07:20
User entered 'No (N)'	System	15 Mar 2021 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Yes (Y)'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'William'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered 'Smith'	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:20:17
User entered (b) (4)	System	05 Mar 2021 17:19:46

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered 'US'	(b) (4) System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:20:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 13:46:16
User entered '1'	System	05 Mar 2021 17:20:26

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:20:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '16/Mar/2021 06:46'	(b) (4) System	16 Mar 2021 13:46:16

US3712013

Folder: SAE USA-US068-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:20:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:43:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:52:11
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:46:16